REACTION

Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

D2-1 Scenarios for usage of the REACTION platform

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1.   Executive Summary

The REACTION project will develop an integrated approach to improved long-term management of diabetes. Included will be continuous blood glucose monitoring, clinical monitoring and intervention strategies, prediction of related disease indicators, risk assessment, and, ultimately, automated closed-loop delivery of insulin. A range of REACTION services will be developed targeted to insulin-dependent type I diabetic patients, and complementary services will be targeted at the long-term management of all diabetic patients. This developmental goal will inevitably have to include consideration of the co-morbidities prevalent in most diabetes patients.

The purpose of this deliverable is to document and describe the requirements collected in the project which encompass the needs and priorities of the users as well as the wider exploitability and scalability requirements. The deliverable provides top-level user requirements in the form of workflows, case management principles and vision scenarios of future use of the REACTION platform.

During the initial discussion of the project objectives and the work plan, it was decided, prompted by the arguments of the clinical partners, to align the REACTION platform functionalities with prevailing clinical practice and medical reality in order to close the gap between today's practice and the potential of the REACTION platform.

As a consequence of this decision it was agreed to include two interview and focus group sessions with the aim of identifying the present clinical workflows in both in-hospital and outpatient settings. The short to mid-term requirements will be given high priority for the initial prototypes of the REACTION platform, and a future scenario thinking session has been carried out in order to provide the long-term requirements.

In REACTION, applications will be developed and deployed to execute comprehensive tasks. Each application serves specific goals and is constructed from a series of standardised workflows and business rules. To ensure a common understanding workflow elements and workflow actions have been visualised with symbols to show linear workflows, business logic workflows, data handling workflows and closed-loop workflows.

The procedures, actions and workflows are very different for the two involved patient groups Outpatients and In-hospital patients. The term 'outpatient' is used in the broader sense, meaning any diabetes patient, Type I or Type II, who is not admitted to hospital, whether his or her care is provided as primary care by physicians in general practice, by healthcare professionals specialising in diabetes care or in outpatient clinics associated with hospitals.

This document describes the requirements collected in the project which encompass the needs and priorities of the users. The short to medium-term improvements envisioned by REACTION for outpatient care and in-hospital care are outlined in Section 4 and 5 respectively. The components of a new care model necessary to embrace the challenges of future healthcare and complement the possibilities of the REACTION platform are described in Section 6. The scenarios forming the basis for the long-term requirement gathering are explained in Section 9 and four long-term, vision scenarios of future healthcare are presented in Section 10.

1.1   Outpatient Care

The number of people with diabetes, both Type I and Type II, is increasing. Combined with an ageing population and the increase in other chronic diseases, closely related to unhealthy lifestyles, this constitutes a major challenge for healthcare services across Europe.

An essential part of diabetes case management for outpatients is glycaemic management, which is not a linear process. Co-morbidities and other clinical factors are involved; there is no clear finish and it remains iterative until death. Between check-ups blood glucose levels are the patients' own responsibility in terms of modifying their diet, taking their medications, measuring blood glucose and adjusting the dosage and timing of insulin, if prescribed. Measuring blood glucose is cumbersome and requires various paraphernalia at hand, and many patients do not carry out the measurements as often as they should. Therefore glycaemic management is generally poor, resulting in increased risk of long-term complications and hyperglycaemic and hypoglycaemic episodes. Real-life examples have been obtained through the results of an interview workshop involving five diabetes patients from Chorleywood Health Centre, one of the clinical partners (CHC). These patients portray five very different, but typical case histories, the common denominator being co-morbidities, usually also chronic.

With REACTION, outpatients' blood glucose levels will be continuously checked by remote patient monitoring, and in case of problems alerts can be generated for both the patients themselves and their carers, formal as well as informal. For insulin-dependent diabetes patients algorithms for estimating the insulin dose needed to adjust for short-term variations in activity, diet and stress level will be implemented.

As a result glycaemic management will be substantially improved and the risk of complications correspondingly reduced.

1.2   In-hospital Care

In-hospital hyperglycaemia has been found to be an important marker of poor clinical outcome and mortality among diabetic patients. The in-hospital care application domain of the REACTION platform will feature a suite of services aiming at Tight Glycaemic Control (TGC) of diabetics in the general hospital wards using continuous glycaemic monitoring and closed-loop feedback to the healthcare professionals at the point of care. Applications for ICU patients are not envisioned, as all vitals of these patients typically are closely monitored, including measuring blood glucose directly on blood samples.

Stress-induced hyperglycaemia can have very adverse consequences for diabetes patients admitted to general wards. Aggressive treatment of stress-induced hyperglycaemia has shown remarkable results in recent years. Continuous Glucose Control is discussed in the context of tight glycaemic control and safe glycaemic control.

To enhance the mutual understanding of diabetes management in a hospital setting a workflow workshop was held at the University Hospital of Graz (clinical partner MUG), providing overviews of daily in-hospital routine and glycaemic management in a general ward, with existing workflows and workflow elements outlined.

With REACTION, the near to mid term improvements for managing in-hospital diabetes patients include:

- Automated patient identification to avoid mistakes
- Performing measurements - Active alarm system, reminder to perform measurements
- Decision making – Electronic decision support system - standardised instructions and decisions
- Data handling - Automated transfer of data to patient record and hospital information system
- Documentation - Electronic paperless data records, centrally managed data repositories, different modes of visualisation with relevant parameters for decision support
- Electronic archiving system

1.3   Trends in Chronic Care

Because of the change in demographics in the EU Member States, with a higher proportion of elderly people and a declining number in the working population, future healthcare faces two serious threats: Healthcare may become severely inadequate or the cost may spiral out of control. This calls for counteractive changes of healthcare provision and of the underlying care models.

As part of the REACTION project a new care model is proposed, which will support future chronic care management and therapy, including diabetes, and encompass the improvements defined for outpatient care and in-hospital care.

Because movement is away from in-hospital care and toward a very high degree of self-management, inclusion and empowerment of the patient must be an essential part of the new care model for chronic care. Other significant factors in the model are: Systems biomedicine, care space evolution, ICTs, personalisation, patient focused organisation.

A central component of care is the planning process which provides a personalised plan for each patient with three main components, a disease management plan, a risk management plan and a lifestyle management plan. The care space integrates the information subspace and the activity subspace.

The visit construction is also very important in the proposed model. Healthcare is provided in the form of televisits and virtual visits in addition to the customary contact visits. These visits place patients in a complex healthcare and social network in which continuous supervision and support are available whenever required.

Another result of the trends in chronic care is the development of attitude where the starting point is the cost-effective attitude. Added are the quality requirements, then the evidence based approach, followed by the

patient-focused approach. Finally model based proactive/predictive care is included, followed by further personalisation considering the socioeconomic and cultural factors of the patients' expectations.

1.4 REACTION Vision Scenarios

Scenarios provide coherent, comprehensive, internally consistent descriptions of plausible futures built on the imagined interaction of key trends. Scenario thinking is a useful method for identifying the key technological, security, socioeconomic and business drivers for future end user requirements.

Four scenarios have been developed to illustrate distinctively different aspects (flips and flops) of future user behaviour in the chronic disease management and therapy domain. The scenarios have been made in response to the question: *How do we perform chronic disease management and therapy using intelligent networked medical devices in 2020 and beyond?*

We have created the four scenarios from two clustering variables: Care Spaces and Driving Forces.

In the "**Care Space**" cluster, we arrive at a large-scale flips and flops as follows:

The *big flip* cluster of **Care Space** describes a healthcare system where prediction, prevention and integrated healthcare are key words. Healthcare professionals work across professional barriers and patients are actively engaged in defining their own care. Healthcare is thus highly personalised and delivered in distinct spaces to optimise the impact. ICT is actively deployed to further support this care model and support patients in effectively managing their disease. ICT also facilitates communication between different groups of healthcare professionals.

In contrast, the *big flop* of the **Care Space** cluster describes a situation where the healthcare system is very conservative and fails to adapt to patients' individual health needs and problems. There are rather strict boundaries between different healthcare professionals and their roles and tasks. Exchanging information about the patient is generally not practised. Although ICT are available they are not used to improve communication or to support patients in self-management and compliance.

Similarly, in the "**Driving Force**" cluster, we arrive at the following large-scale flips and flops:

In the *big flip* **Driving Force** cluster, financial incentives are optimised and used to promote healthy living and in providing the most effective care to patients; benefits are sometimes prioritised over costs but patient involvement can be actively used to reduce costs in other areas. Healthcare is publicly funded and even some lifestyle initiatives are publicly funded. As there is great social pressure on people to adopt healthy lifestyles, insurance companies have found a new market in offering insurance to support wellness and prevention initiatives. Also, patients increasingly use patient-to-patient groups to support them in dealing with their disease in a cost effective way.

ICT facilitates - and thus improve - communication between healthcare professionals and patients

In the *big flop* **Driving Force** cluster, financial issues have an immense influence on the extent of treatment and therapy that are available and cost effectiveness is always the priority. Costs weigh higher than benefits and healthcare provision is based on a result-oriented principle where healthcare professionals are paid according to the results they achieve, i.e. healthy patients. Public healthcare tends to be increasingly privately funded (including co-payments) and the publicly funded healthcare may be based on a personal health budget for life, which basically means that there is a set limit to how much a person "can cost" public healthcare over a lifetime. Even so, insurance companies do not see any potential benefit in supporting wellness and healthy living.

The underlying scenario structures for the four possible combinations are:

Proactive Healthcare + Cost-focused (Getting by!)

Though healthcare models have been changed to focus on proactive and personalised care, healthcare budgets are under aggressive pressure from the increasing number of patients with long term conditions and the ever increasing cost of drugs. Healthcare professionals work across professional barriers in multi-disciplinary agile teams, but always under strict cost control. Although personalised healthcare has high priority and patients are positive about healthcare ICT and feel that they can help them lead normal active lives with their condition, successful implementation has been limited and patients are not engaged in defining their own care. There is a lack of patient-to-patient communities where patients can exchange information about their diseases and thus little social pressure to change lifestyle. Due to the cost focus, neither public healthcare nor insurance companies supports programmes for healthy lifestyle initiatives, which are left to the individual.

Proactive Healthcare + Patient-centric (Health Odyssey)

Proactive and predictive healthcare has been instrumental in reducing the total cost of healthcare, and politicians have realised the necessity of making long-term investment in ICT infrastructure to this end. Adaptable ICT solutions that monitor vital parameters defining the overall state of patients with chronic diseases are actively deployed to support the personalised care model. The ICT solutions also support patients in managing their disease more effectively with virtual visits and televisits. There is focus on providing proactive care with the particular aim of preventing chronic diseases and their associated long-term complications. Risk assessment is an integral part of chronic disease management and therapy. New care models for managing chronic illnesses are in use which seamlessly interrelate the information and the activity spheres. Although public healthcare systems provides healthcare as needed for all, non-hospital healthcare delivery has increased dramatically, and insurance companies and healthcare authorities see clear advantages in supporting wellness and prevention initiatives.

Conservative Healthcare + Cost-focused (Play it Safe)

The healthcare system is conservative and is not adapting to patients' individual health needs and problems. Boundaries between different healthcare professionals limit the use of multidisciplinary teams and the exchange of medical information about patients is not practised. Due to economic constraints, new care models have to be adapted to existing care spaces before they are deployed. Patients are not involved in any decision making processes regarding their care. Although ICT are available they are not used to improve communication or to support patients in self-management and compliance. There are great concerns about rising costs of new treatments and cost is always compared to the expected yield.
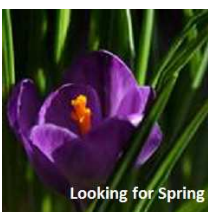
Conservative Healthcare + Patient-centric (Looking for Spring)

In the traditional publicly funded healthcare system, financial incentives are optimised and used to promote healthy living and to provide the most effective care to patients. Reimbursement systems are highly focused on care efficiency. Changes to healthcare models are difficult to carry through and risk assessment only plays a minor role in relation to chronic disease management. Patients are generally sceptical about healthcare ICT and feel that they are too intrusive and threaten to take over their lives. Healthcare professionals do not consider ICTs to be adaptable to chronic disease management. There is great social pressure on people to adopt healthy lifestyles, and insurance companies offer insurance to support wellness and prevention initiatives. Patients increasingly use patient-to-patient groups to support them in dealing with their disease in a cost effective way.

Together with the outcome from the outpatient and in-hospital workshops the scenarios will provide the main framework for the iterative requirement engineering process.

2.   Introduction

2.1   Overview of the REACTION Project

The REACTION project will develop an integrated approach to improved long term management of diabetes; continuous blood glucose monitoring, clinical monitoring and intervention strategies, monitoring and predicting related disease indicators, complemented by education on life style factors such as obesity and exercise and, ultimately, automated closed-loop delivery of insulin.

The Reaction project seeks to use the great potential of new technologies to address the major societal challenges in coping with the increasing number of citizens suffering from insulin-dependant diabetes. The success of the new technological applications depends heavily on the acceptance from end-users, i.e. patients, relatives and professional carers as well as the acceptance from healthcare commissioners, business stakeholders, and regulatory authorities.

Technically, the REACTION platform will feature an interoperable peer-to-peer communication platform based on a (SoA) service oriented architecture where all functionalities, including devices, are represented as services and applications consist of a series of services orchestrated to perform a desired workflow. The REACTION platform also features a Model Driven Application Development environment based on extensive use of dynamic ontologies and advanced Data Management capabilities with algorithms for clinical assessment and rule-based data processing.

A range of REACTION services will be developed targeted to insulin-dependent Type I diabetic patients. The services aim to improve continuous blood glucose monitoring (CGM) and insulin therapy, by both basal dose adjustment and contextualised glycaemic control based on patient activity, nutrition, stress level, etc. Decision support will assist healthcare professionals, patients and informal carers to better manage diabetes therapy and make correct choices about e.g. good blood glucose control, nutrition and exercise.

REACTION will further develop complementary services targeted at the long term management of all diabetic patients, Type I and Type II. Integrated monitoring, education, and intervention will ensure all patients remain at healthy blood glucose levels, with early detection of onset of complications.

Security and safety of the proposed services will be studied and necessary solutions to minimise risks and preserve privacy will be implemented. Legal framework for patient safety and liability as well as privacy and ethical concerns will be analysed and an outline of a policy framework will be defined. Moreover, impacts on health care systems will be analysed and health-economics and business models will be developed.

2.2   Purpose, Context and Scope of this Deliverable

In this section we discuss the purpose and context of the deliverable. We also discuss the work process that has been undertaken and, in particular, the additional work that has been agreed in order to facilitate the communication across the well-known medical-technical gap while acknowledging the different forms of expression and different requirements on each side.

2.2.1   Purpose and Context

The purpose of this deliverable is to document and describe the requirements collected in the project which encompass the needs and priorities of the users as well as the wider exploitability and scalability requirements taking into account the technical constraints as well as the safety, socio-economic and legal acceptance and the deployability of the REACTION platform in real Public Healthcare Systems. The deliverable documents the work undertaken in task T2.1 Scenario thinking.

The deliverable provides top-level user requirements in the form of use-cases (workflows), case management principles and vision scenarios of future use of the REACTION platform. The next step produces technical oriented scenarios focussing on the deployment and use the REACTION platform. The technical scenarios address technical questions referring to the platform and its components. Technical scenarios have been developed through discussions in focus groups and detailed requirements are formulated in task T2.2 Initial requirements specifications.

2.2.2 Scope

Scenarios provide coherent, comprehensive, internally consistent descriptions of plausible futures built on the imagined interaction of key trends. The purpose of Scenario Thinking in REACTION is to challenge the preconceived notions among the medical professionals of the future and to afford the flexibility to change those notions. Creating scenarios of end-user behaviour and interaction with platform functionality is a useful instrument for identifying the key technological, security, socio-economic and business drivers for future end-user requirements.

However, during the initial discussion of the project objectives and the work plan, it was desired by the clinical partners to have a close alignment of the REACTION platform functionalities with prevailing clinical practice and medical reality. It was argued that any new clinical workflow must be rooted in the medical and clinical reality and the gap between today's practice and the potential of the REACTION platform would be too large to be realistically validated. This gap could be closed by initially focusing on clinical workflows underpinned by a short-term look at potential improvements from the use of the REACTION platform.

From a technical-scientific point of view, it was argued that the short-term approach may not lead to real breakthrough opportunities in the development of new technologies, such as SOA Service Oriented Architectures, semantic interoperability and dynamic ontologies.

It was thus agreed that the iterative method for the REACTION project is augmented to encompass both views and hence bridge the gap in the course of the project. This will be achieved by adding two interviews and focus group sessions with the aim of identifying the present clinical workflows in both in-hospital and outpatient settings followed by an analysis of the potential for improvement offered by using the REACTION platform. This exercise will provide clear short to mid-term requirements, which would root the platform functionality solidly in clinical and medical practice and thus give credibility to the results in the medical domain. The short to mid-term requirements will be given high priority for the initial prototypes of the REACTION platform.

The future scenario thinking session has been carried out in order to provide the long-term requirements, which should enable and support the full range of future diabetes management, where inclusion and empowerment of the patient has to be an essential part of any chronic care. This requires the re-engineering of care and the design and implementation of a new care model which underpins sustainable healthcare in the future. The developed scenarios will thus be placed in the context of sustainable patient-centric chronic care. This exercise has provided long-term requirements, which will pose great challenges to the platform architecture, interoperability and interconnectivity as well as in service composition and execution and thus give credibility to the results in the ICT domain as well as in the medical domain. The long-term requirements will be given priority for the later prototypes of the REACTION platform.

2.2.3 Procedure

The slight change of scope of the requirements engineering process has led to the following revised procedure:

Step 1 (task T2.1 responsible IN-JET):

The first step undertaken has been a user centric requirements method with a combination of interviews and focus groups. This was carried out in two workflow workshops, which took place at Chorleywood Health Centre (CHC) in Hertfordshire, UK on April 29th, 2010 (Outpatients) and in Graz, Austria on May 5th (Inpatients). In each workshop clinical experts and end users were interviewed about their future needs and wishes for new workflows in diabetes monitoring and management using REACTION. Selected partners were invited to pose detailed questions related to their own work packages and technologies.

The clinical partners have prepared descriptions of typical workflows. The findings from the workshops and the ensuing work are documented in sections 4 Existing and Future Workflows in Outpatient Care and 5 Existing and Future Workflows in In-hospital Care below.

With the second method we elicit long-term visions about radically new healthcare systems and case management with a horizon of 10 years and more. These visions were elicited in the scenario workshop held at CHC on April 30th using a modified Delphi technique called IDON. The organisation of the vision scenario workshop is described in section 9. The results are presented in a number of storyboards.

Step 2 (task T2.2 responsible FORTH-ICS):

Using the workflow descriptions and scenarios, each WP leader/partner is responsible for extracting the detailed technical requirements and evaluating their architectural influence. The aim is to create a significant number of detailed requirements, with priority of implementation being managed by a web-based issue tracking tool (the JIRA tool). The WP leaders/partners are organising internal workshops with their technical staff to discuss the workflows and scenarios, and thereby extract the relevant requirements for their area and insert them in the requirement database.

Step 3 (task T2.3 responsible FORTH-ICS and CNET):

IN-JET, CNET and FORTH-ICS will lead a final step of requirements engineering and documentation together with the WP leaders. During this phase all WP leaders will identify and resolve requirements that are conflicting, overlapping, obsolete, have errors or in other ways need to be modified. The consolidated list of requirements will be documented in D2.5 "Initial requirements report".

The REACTION project will develop 1) a technological platform and 2) pilot applications based on that platform so the requirements must contain elements that define both platform functionality and pilots.

2.3 The Iterative Method

One of the core tasks of user-centred design is to negotiate and facilitate the communication across the well-known user-developer gap while acknowledging the different forms of expression and different requirements on each side, which was also experienced in the REACTION project. The literature has many examples demonstrating that end-users have to bridge the large gap in understanding especially in projects that apply a waterfall model. Clark, Lobsitz & Shields, (Clark1989) show that evolutionary or iterative approaches greatly reduce this gap.

2.3.1 User-Centric Design Methodology

The requirement engineering process in REACTION is inspired by the principles of the ISO 13407 "Human-centred design processes for interactive systems" standard. This standard provides guidance on human-centred design activities throughout the life cycle of computer-based interactive systems.

The methodology calls for comprehensive iterative requirements and stakeholder analysis based on initial requirements gathered from clinical practice and issue identification, state-of-the-art research into revolutionary chronic disease management as well as medical and clinical scenario thinking.

In accordance with this generally accepted process, the REACTION project has adopted an evolutionary requirements engineering, specification and design methodology underpinned by a strong user-centric development that complies with the following template in each iteration:

- User requirements engineering and refinement
- Architecture design specification and refinement
- Clinical protocol and medical context planning
- Technologies research and development to implement architecture
- Integration and prototype development and field trial preparation
- Field trials in clinical domains
- Conformance testing, usability evaluation and user acceptance testing
- Lessons Learned and change analysis

The specific methodologies that will be used include evolutionary design and refinement re-engineering. Lessons Learned obtained during project progress will be used to arrive at adjustments to the initial requirements incorporating and inclusion of emergent requirements. The project partners will be continuously informed of the requirement engineering process in order to enable the necessary and timely modification of design specifications and possible re-engineering of affected modules.

The process thus supports the chosen methodology by focusing on the expectation of users, e.g. clinicians that would like to see concrete applications developed and are less interested in architecture and technology and more interested in the clinical usability.

2.3.2   Objectives

Specifically the objectives of the iterative process are to:

- Elicit the generic and specific domain requirements for the full technical, societal and business realisation of the project results in the domain of Public Health Services.

- Maintain a continuous study of the medical, clinical, technological, legal, regulatory, and market developments affecting the REACTION platform as the project progresses.

- Evaluate the potential clinical value and validate the impact on clinical workflows from REACTION applications and field trials in WP8 and its affect on the requirements.

- Evaluate the early adoption of the platform in relevant healthcare environments taking into account socio-economic and regulatory boundary conditions derived in WP9.

- Re-formulate the specific user requirements in terms of updated functionalities from each of the sub-systems. This procedure will feed back results from all workpackages to the (re)specification phase enabling the re-engineering of requirements for best technical outcome, conformity to user needs, innovation and market potential.

2.3.3   Foundation for Requirements Gathering

The work in this task will aim to achieve a systematic foundation for deriving all stakeholder requirements and subsystem functionality requirements. The foundation is derived from the two user workshops and the scenario thinking workshop.

- Functional requirements - what is required from different user perspectives?

- Security and safety requirements – based on the security analysis and device risk analysis which include the formulation of a set of security policies.

- Business requirements – what is required to live up to market and business needs, what are required to satisfy existing and new stakeholder involvement and how will current business practices be supported?

- Societal requirements - including requirements related to ethics, inclusion, quality of use, professional liability, regulatory needs, etc.

Functional requirements are related to the use of the REACTION platform in clinical settings. It will involve the most important aspects of user expectations short-term, mid-term and long-term. The aim of this work is to capture functional requirements in such a way that they can drive architectural and technical decisions and be used to validate the various sub-systems and the entire architecture.

3.   Definitions and Terminologies

3.1   Workflows

A workflow is a model to represent real work for further assessment, e.g., for describing a reliably repeatable sequence of operations. More abstractly, a workflow is a pattern of activity enabled by a systematic organization of resources, defined roles and information flows, into a work process that can be documented and learned. Workflows are designed to depict processing intent of some form, such as physical transformation, service provisioning, or information processing.

A workflow consists of a sequence of connected steps. It is a depiction of a sequence of operations, declared as work of a person, a group of persons[1], an organization of staff, or one or more simple or complex mechanisms. For control purposes, workflow may be a view on real work under a chosen aspect[2], thus serving as a virtual representation of actual work. In manual workflows, the flow often refers to a document that is being transferred from one step to another.

Workflow concepts are closely related to other concepts used to describe organizational structure, such as silos, functions, teams, projects, policies and hierarchies. Workflows may be viewed as one primitive building block of organizations.

In REACTION, applications are developed and deployed to execute comprehensive tasks. Each application serves specific goals and is constructed from a series of standardised workflows and business rules. An example of this could be monitoring of a patient's correct insulin intake. One workflow consists of reading blood glucose levels and dietary intake at determined intervals. Another workflow will determine recommended bolus dose (fast acting) insulin from these readings and feed it back to the patient. A third workflow will read the actual insulin intake whereas a fourth workflow will compare the two and fuse the information to various stakeholders. Application are developed using ontologies. An ontology describes the objects involved (devices, users, rule sets, repositories, etc), the security model to be used and the run-time environment. Information processing and information flows are developed in the form of the conceptual domain models, and application developers have direct access to software artefacts generated from modelling. This makes application development and deployment more efficient.

3.2   Workflows in Healthcare

Medical informatics and software engineering researchers have studied how to use software technologies to define, analyse, automate, and provide decision support for healthcare workflows. Software systems that facilitate healthcare workflows (also referred to as "medical guidelines", "procedures", "protocols", or "processes" in the literature) are often developed through integration of medical devices and healthcare information systems (HIS).

A group of researchers at the Siemens Corporate Research Inc. in Princeton, NJ, USA have studied various terminologies for describing healthcare workflows (Song2006). The group interviewed a large number of medical professionals and found that all the parties easily agreed that improving healthcare workflows is very important for improving healthcare quality and efficiency. However, the semantics behind the terminologies as they are intended by the different parties are rarely the same e.g., what is actually meant by "workflows"). Different parties often focus on different kinds/aspects of healthcare workflows, and, because of the different characteristics of those workflows, have different goals and thus take different approaches.

Workflow research and development activities can be classified into two major relevant areas:

- Workflow development: To define formalized, validated medical workflows that can be shared among the healthcare providers, which will be the initial work performed in the clinical trials ;

- Workflow execution: To facilitate the practice of the workflows: A healthcare workflow management system will be provided by the REACTION service execution engine which provides workflow definition and interpretation mechanisms to support the workflow executions.

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[1] ISO 12052:2006
[2] ISO/TR 16044:2004

3.2.1 Healthcare Workflows in REACTION

From the healthcare application perspective, computer-aided healthcare workflows can be classified into the following groups:

Healthcare Workflows	Workflow Properties	Examples	Relevance for REACTION
Administrative: For managing patients and healthcare organization.	Single user or distributed across organizations. In general, it is quite mechanical and routine.	• Check-in/Out, Discharge, • Bed assignment, • Quick-check-in, • Newborn paper work.	• Relevant for contextualisation and interoperability with back-end HIS systems such as EPR. • Part of the short to mid-term workflows that needs to be supported for clinical validation • Provide relevance and realism to the prototype demonstrators
Financial: For managing the revenue of healthcare organizations.	Contract complexity. Quick response to changes in Medicare and new medical admin organizations.	• Insurance follow-up • Better claim coding	• Relevant for reimbursement schemes and potential remuneration of IPR of medical models. • Provides the hook for integration into real-life healthcare systems
Clinical operational: For executing the tasks for diagnosis and treatment	Exposes software vendor to liability. In general, it is quite mechanical and routine.	• Order/Administer medications • Patient monitoring • Collaborative	• Relevant for outpatient and to some extent for in-hospital workflows • Important for traceability issues and collaboration among healthcare professionals
Clinical decisional: For patient assessment, disease diagnosis, and treatment plan development.	Requires human intelligence and medical knowledge. Computerizing them will expose software vendors to liability.	• Cough, • Headache, • Chest pain • Abdominal pain	• Relevant for the essence of the short to mid-term workflows in both outpatient and in-hospital domain • Relevant for multiple devices • Important for liability issues
Clinical therapeutic: Needs to have the functions of both clinical operational and clinical decisional.	Require staff team work. Include both long and short duration processes.	• Cancer treatment • Diabetes Mellitus • Physical therapy • Disease management • Longitudinal studies	• Relevant for inclusion and engagement of patient in self-management and life-style changes • Facilitates disease management in vision scenarios • Relevant for inclusion of risk models and risk assessment
Laboratory: For acquiring data that supports the diagnosis	Mechanical. Some require skills and reasoning	• Sample collection • Image analysis	• Relevant for sensor design and Personal Area Networks

Table 1 Healthcare workflow groups (Song2006) and relevance for REACTION

All of the identified workflows have relevance for the REACTION platform and must be considered and reflected in the requirements and the protocols for the clinical trials, also those that do not have a technical implementation.

3.2.2 Development Challenges

Today's medical workflow management systems are limited to single user, non-intelligent workflows, single user, medical guideline automation or analysis of workflow-related financial data.

It seems that medical workflow management systems are much less successful implementing distributed workflows that are multi-user in nature and may cross organisations. Two possible reasons have been identified for this:

- Mismatched underlying models (computer-aided workflow model vs. medical staffs' working model)

- Medical workflow's execution must be maintained to be consistent with real world medical events regardless of what reminders or alerts indicate

In order to provide the innovative workflows supporting services as envisioned in REACTION, great care must be taken not to focus on single user or non-intelligent workflows, rather on the visionary, multi-user, cross-organisational, and intelligent workflows that will support future personalised case management in outpatient regimens underpinned by strong emphasis on patient empowerment.

Hence, the technical scenario focus groups have to identify the functional and non-functional requirements with a view to develop the actual software and applications that will make the REACTION platform able to support and execute these future workflows. In this process it will be useful to take the following challenges to applications into consideration:

- Data Aspects: Different technologies and data value scales, collection of data versus performance, existing medical informatics standards, terminologies and ontologies.

- Integration: Different workflows, event forecasting and data propagation, feasibility and execution.

- Legal/regulatory: Approvals, responsibility, IPR.

- Usability: Efficiency without disturbance, no overloading of tasks, guidance for priority with easy switching, security.

- Multiple views: Different medical roles, aspects and concerns, different context and activity.

- Adaptability: Different healthcare environments and healthcare providers.

- Maintenance: Medical advances, legislative and regulatory changes.

Moreover, a number of challenges directly related to software development must be considered.

- Validation: Completeness, execution feasibility/reliability and syntax.

- Model mapping: Integration of medical guidelines with other medical information systems.

- Formalising the medical guidelines: Formalise values for analysis and execution.

- Support a variety of control/execution flows: Flexibility, especially for exceptions, recovery and rollback mechanisms.

- Support adaptability: Adaptability for different medical purposes, healthcare roles and healthcare organisations without too much overhead.

- Support capturing real-time information: Identification and adjustment of out-of-date medical and patient information without too much overhead.

These challenges will be handled in task T2.2 Initial requirements specifications.

3.3   Workflow Terminology

In this chapter, we will establish a terminology of how workflows are to be built in the REACTION context, and how they can be construed by progressively smaller units. This approach will help us in defining system requirements and software architecture from a selection of specific and generalised workflows. But first, we will look at the special case of workflows in healthcare.

3.4   Workflow

A workflow is a model to represent real work. A workflow may thus be seen as any abstraction of real work, segregated in work elements, work split or other types of ordering. Workflows are procedures established with the aim of achieving certain objectives within an application. They can be personalised through parameterization thus adapting to the needs of any user (patient, healthcare professional, etc.).

Workflows can be recursive, so that one workflow may encompass other (typically more simple and standardised) workflows, each of which can have an independent life in another context.

Workflows may contain complex business logic or include stubs to very complex models and decision support systems used to identify and select appropriate and optimised solutions in highly complex contexts.

3.4.1   Workflow Elements

Workflow elements are simple, standardised activities or business processes that typically are used (and reused) to build more comprehensive and complex workflows. Workflow elements are often re-occurring in several forms within a workflow and may be re-used across a wide variety of workflows. Workflow elements may contain business logic to identify and select solutions based on simple business rules involving several objects.

3.4.2   Workflow Actions

Workflow activities are construed by a series of Workflow actions. These are very simplified, linear processes acting on a limited number of objects. Workflow actions do not contain business logic because any business logic is handled at the workflow element level. Likewise, workflow actions cannot be recursive. Recursive action is also handled at the workflow element or workflow level.

3.5   Symbols and Descriptions

Workflows and workflows elements are described using standardised symbols. For use with the Microsoft Visio© drawing tools, a REACTION stencil has been created.

3.5.1   Workflow Symbols

Basic symbols to be used to describe various workflows are the following:
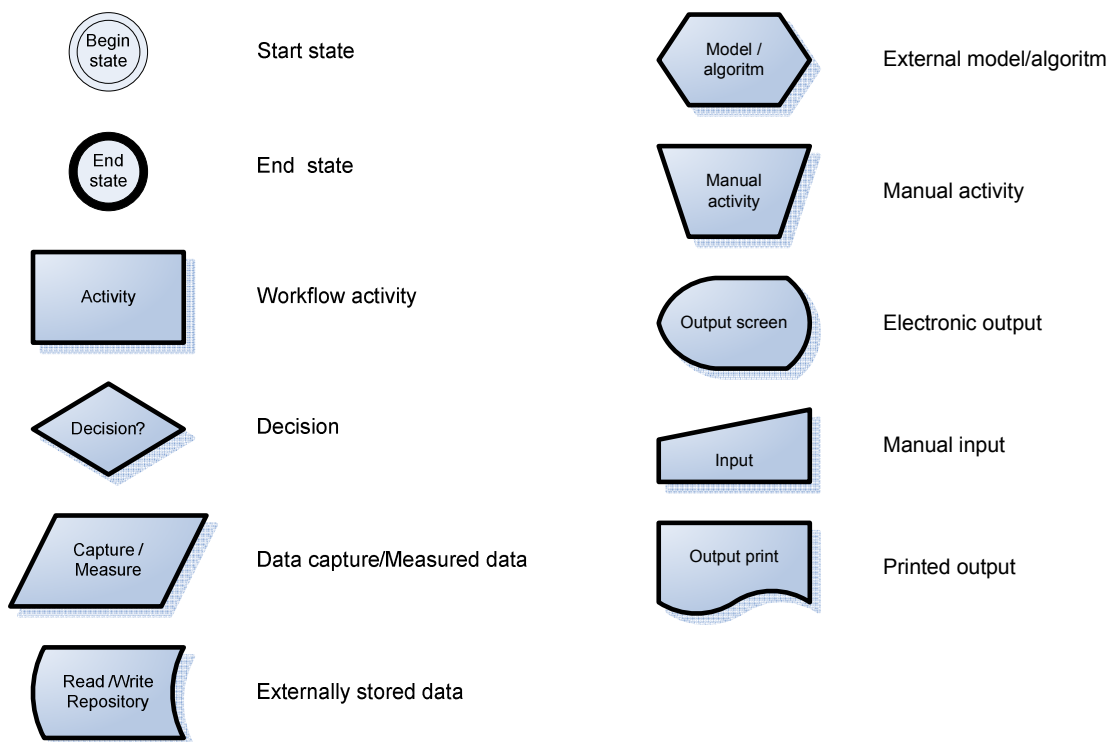
Figure 1 Workflow symbols

3.5.2   Linear Workflows

Workflows are constructed and described using the above symbols to represent the sequence of activities that needs to be performed. A single activity workflow can have the following structure:
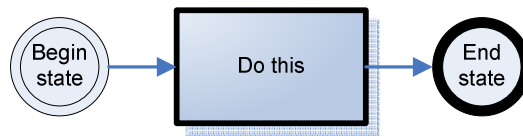
Single activity workflow

This workflow represents a single action required to bring the object from a state A to a state B.

Such simple workflows are rare, even in terms of workflow elements. Often there are many more activities involved:
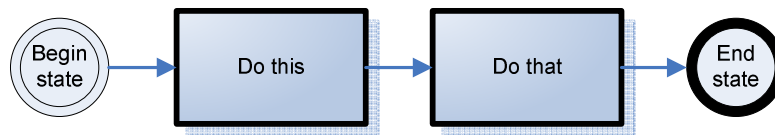
Multiple activities workflow

Some workflows are repetitive. Repetitive workflows are repeated a number of times:
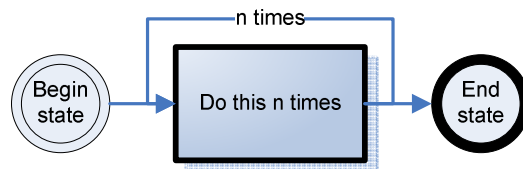
Repetitive activity workflow

They should not be confused with recurrent workflows because recurrent workflows are executed until a certain condition is fulfilled. Recurrent workflows will be discussed in the next section.

3.5.3   Business Logic Workflows

The most typical workflows to be implemented by REACTION will include some kind of business logic or intelligent decision making / decision support.

Business logic describes how objects (patients, healthcare professionals, physiological models, data repositories, etc) interact with one another in real life. Business logic comprises business rules that express business policy or clinical practice and the associated workflows.

Business logic is necessary to describe a workflow, which changes scope depending on a specific event. For example, the activities to be performed depend on the outcome of an analytical process:
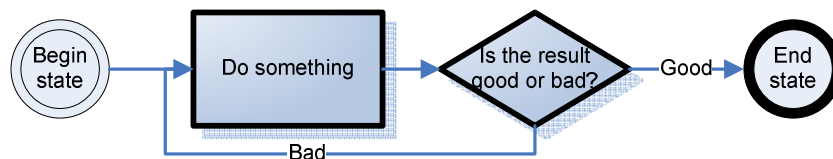
Repeat an activity until the result is satisfactory

In this case, the activity is repeated until the outcome is satisfactory.

A derivative of this case is a workflow, where the activity to be performed depends on a value (which for the sake of simplicity is entered by a user). The value could be the patient's age and the activity could be a specific age-dependant advice.

Perform either one or the other activity depending on a value entered manually from i.e. a keyboard.
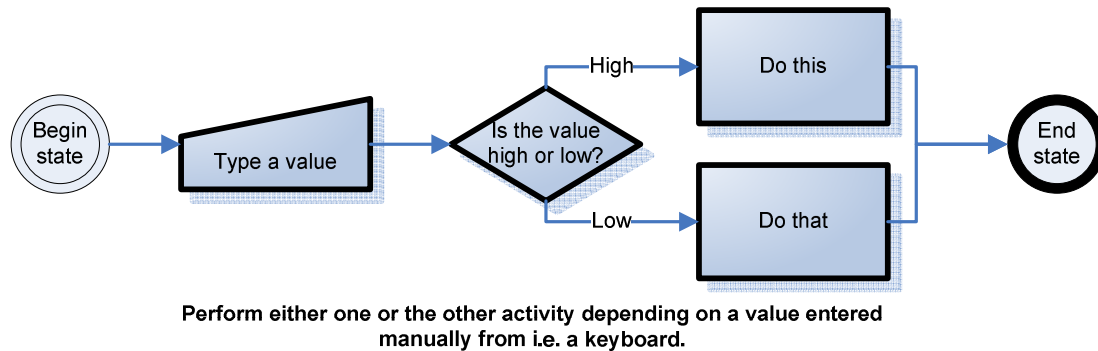
3.5.4   Data Handling Workflows

With the highly advanced features of system interoperability incorporated in the REACTION platform, a large part of the workflows will be dealing with data input and output, data fusion, data contextualisation and thus information and knowledge management.

Complex data handling workflows depends on the actual clinical workflow and will be the subject of subsequent chapters. Here, we will limit the discussion to presentation of a workflow using data input and output. The following figure shows an example of a data handling workflow:

Measuring glucose level and storing data in Electronic Patient Record. Patient is informed via mobile phone
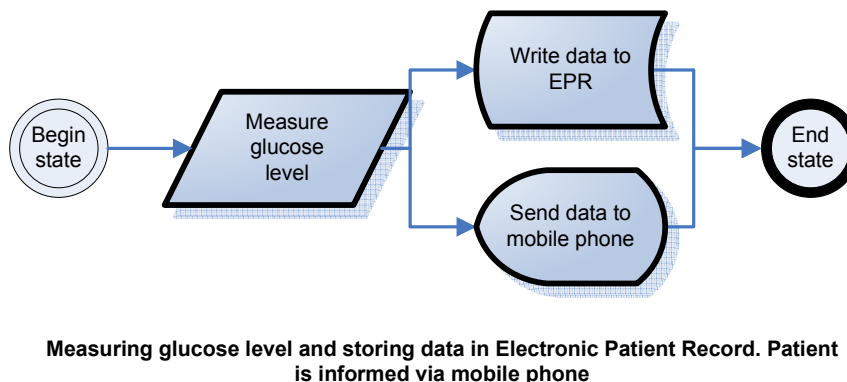
3.5.5   Closed-Loop Workflows

The workflow is always surrounded by the "Begin state" and the "End state". The workflow thus takes an object from state A to state B. For example, the workflow could take a patient from a state of "Disease" to a state of "Healthy". A broken arm will require a workflow containing a series of activities (X-ray, stabilization, apply cast, prescribe pain killer, follow-up check, removal of cast, rehabilitation). This workflow will take the patient from a status of "disease" to a status of "healthy".

In the case of chronic disease, the patient will not be able to reach the state of "Healthy". Rather, the two possible states are "Mortality" and "Stabilised". In the REACTION we will only work with the "stabilised" state.

A vital element of REACTION is how we can monitor for the impending change from *Stable* to *Unstable*. Stable is not an endpoint, merely a respite. There is thus only one End State here "mortality", and the workflow is a series of loops in an onward journey. We can define aspects of the workflow but we cannot lose sight of the change from Stable to Unstable as being very important.

A "closed loop" workflow can be visualised as seen in Figure 2. In this example, the workflow sets out a monthly control of HbA1c followed by a possible decision change of therapy.
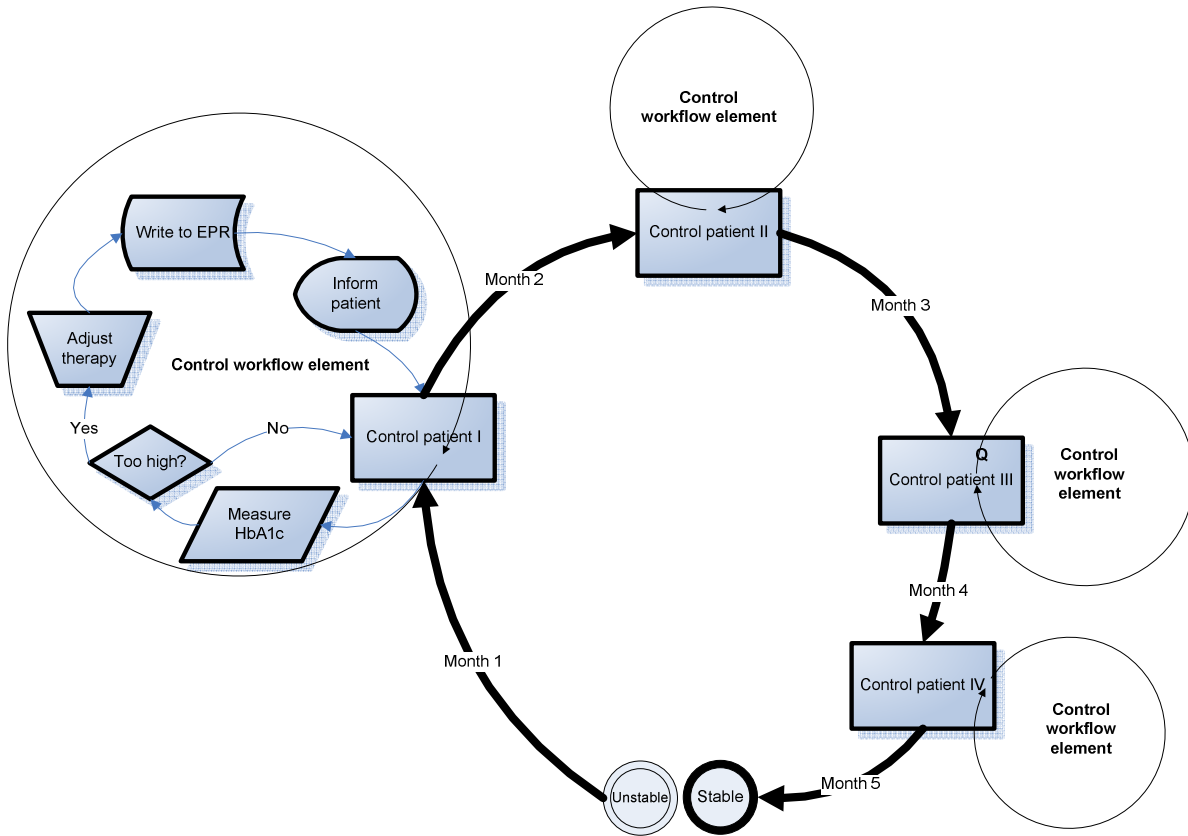
Figure 2 Closed-loop clinical workflow

4.   Existing and Future Workflows in Outpatient Care

4.1   Description of the Domain

Healthcare services across Europe face massive challenges in the future as the European population is growing older, more and more people have chronic diseases and the general needs and expectations for efficient and effective healthcare services increase. These challenges concern both the quality of healthcare and the availability of resources – human as well as economic resources – to deliver healthcare services. Most European Member States are likely to face a severe shortage of healthcare staff to care for the growing number of patients.

Diabetes Type I (insulin-dependent Diabetes Mellitus) accounts for 5-10 % of all diabetes cases, while the remainder of diabetes case, 90 – 95 %, are Type II.

The number of people with diabetes, both Type I and Type II, is increasing, in the EU as well as in the rest of the world. A common denominator for diabetes of either type is that it is almost never a patient's only disease. Co-morbidity is the rule rather than the exception, and very often these other illnesses are also chronic.

4.1.1   Demography

The demographic development in the EU Member States shows a decrease in birth rate and increase in life expectancy rate.

This demographic development means that we will have an ageing society in EU; the proportion of elderly people (65+ years) will continue to rise, while the proportion of the working population will decline. This will have a significant impact on issues related to health and the delivery of healthcare. Elderly people need more care compared to the younger generation, and at the same time a lack of healthcare professionals, exacerbated by a smaller working population, will put enormous strain on the healthcare systems in Europe.

From the economic perspective, a smaller working population means less tax revenue to finance the public healthcare system, thus placing additional strain on the resources within public healthcare delivery. Public healthcare systems face serious challenges in controlling and managing healthcare costs while at the same time meeting healthcare needs. At the same time, the general public is likely to have higher demands requiring an efficient healthcare system. Public demands of high quality care, easy access and fast and reliable treatment are most likely to become even more firm and influential in the future.

4.1.2   Lifestyle and Chronic Diseases

A serious problem facing all EU Member States is the increasing number of people with chronic diseases. This factor is closely related to an unhealthy lifestyle. However, cultural and socioeconomic factors are also linked to development of lifestyle diseases and importantly also to how well the disease is managed.

How well you live with a condition, your likelihood to die from it, depends to a large degree on where you live, your ethnicity and socioeconomic background. This clearly demonstrates the cultural and socio-economic aspects of health, but also that good management (such as healthy lifestyle and proper monitoring) of a certain condition can be a matter of life and death. In general, heart disease is much more common in deprived areas, while treatment and care is often best in affluent areas.

There should therefore be no doubt that the so-called lifestyle diseases have serious consequences and may be life threatening if they are not treated and handled correctly. Lifestyle diseases include Type II diabetes, stroke, obesity, ischaemic heart disease and atherosclerosis and diseases associated with smoking and alcohol and drug abuse. In fact, according to the World Health Organisation, an estimated 80% of heart disease, stroke and Type II diabetes, and 40% of cancer, could be avoided if common lifestyle risk factors were eliminated. Moreover, up to 86% of deaths in Europe are caused by largely preventable chronic diseases[3].

Lifestyle diseases are also increasingly affecting the younger population, with increased incidences of obesity, hypertension, high cholesterol and Type II diabetes. An obvious consequence of this trend is that this group will need lifelong healthcare in order to manage their conditions. If not managed correctly, it can

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[3] http://www.euro.who.int/mediacentre/PR/2006/20060908_1

lead to serious health problems that may affect the group's ability to work, thus indirectly contributing to a further reduction of the workforce.

The gravity of lifestyle diseases is becoming more and more visible and is widely recognised by the authorities. More information about healthy living and the negative affects of unhealthy foods, lack of exercise and stress on the health is becoming available. However, there is still a great deal of imbalance in relation to the availability and access to this type of information between different EU Member States, as well as within different regions of specific countries. Likewise, concrete initiatives to promote a healthier lifestyle are still lacking. Most initiatives, guidance and advice are directed towards people who have already been diagnosed with e.g. diabetes or chronic obstructive pulmonary disease. Moreover, diseases such as diabetes can significantly increase the risk of stroke, heart disease, loss of sight, peripheral neuropathy, foot amputations and kidney failure.

4.1.3   Remote Accessibility to Chronic Disease Management and Therapy

The aim of the REACTION project is to develop operational healthcare networks, which will improve diabetes management and therapy. To accomplish this, the co-existence of other (chronic) illnesses must be taken into account. This is the case for outpatients as well as for in-hospitals, and for diabetes Type I and Type II.

4.2   Diabetes Case Management in General Practice

Glycaemic management of diabetic patients in General Practice as demonstrated in the clinical flow diagrams is not a linear process. It also involves other co-morbidities and other clinical settings which affect the pathway; there is no clear finish and it remains iterative until death. Diabetes is progressive and the pathway becomes ever more complex as the condition deteriorates: co-morbidities develop that complicate and increase risk; complications of the disease evolve and require management and treatment; management of other conditions becomes more complicated and introduces higher levels of risk. Requirements of workflow can be quite different for patients at different stages in the development of the disease, different types of the disease, their co-morbidities, and management of complications.

1. Patient presents either as a known diabetic or having just been diagnosed following symptoms or opportunistically

2. Annual or six monthly reviews as per template – in line with national standards

3. Review of results – therapy altered as necessary – diet and lifestyle reinforced at each visit. If complications detected then referral to specialist service
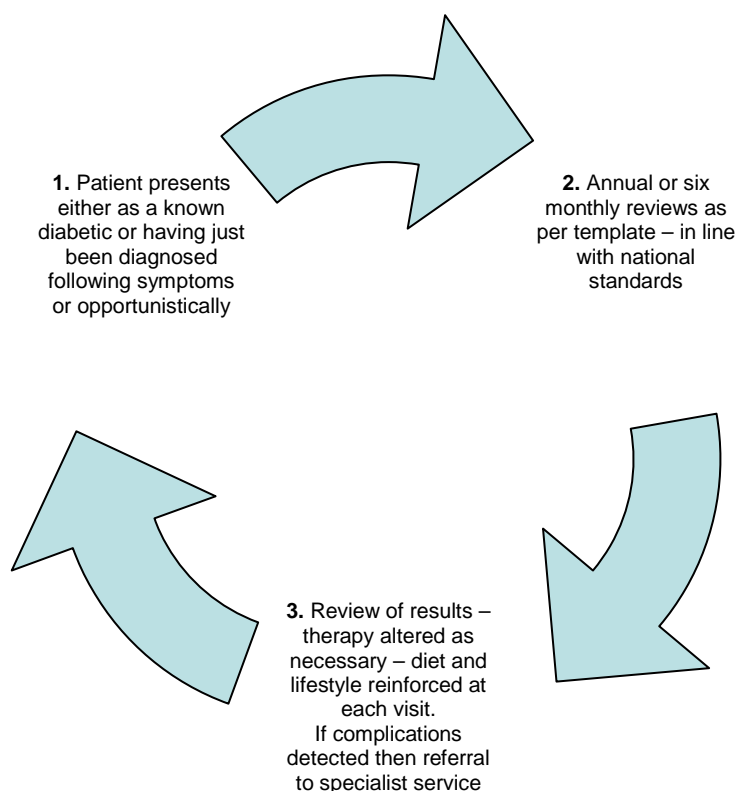
Figure 3 Iterative diabetes pathway

4.3   Hosting Institution and Case Studies

Chorleywood Health Centre (CHC) is a medium sized general practice based in an affluent area North West of London. The majority of its 6000 patients are elderly and patient care is well managed. The practice achieves high QOF[4] scores, taking 96.4% of the total points available – 0.7% above national average. It achieves 98.2% of points available for Diabetes Mellitus. In total there are 145 patients on the disease register for Diabetes – 27 Type I, 118 Type II and 45 are currently on insulin therapy.

The health centre is staffed by a multi-disciplinary team. The practice also provided on-site physiotherapy and counselling services. The practice is housed in a purpose-built building which replaced its predecessor after a flood in 1997. The building was developed specifically to exploit technology and telecommunications to deliver healthcare and the team have been using technology as tools to help them with their work for some time. Except for regulatory documentation the practice is paperless.

As part of the first step towards user centric requirements gathering, a workshop was held at CHC on April 29th 2010 with a combination of interviews and focus groups. Five diabetes patients from the Health Centre had agreed to be interviewed during the morning session in the presence of CHC healthcare professionals and 4 persons from the REACTION project. The participants were deemed representative of patients at different stages of the disease, with different types of the disease, and having complications and co-morbidities. The summary of the interviews were presented to the rest of the consortium partners in the afternoon followed by Q&A session and discussion.

Below is a summary of the case histories, interviews and conclusions for these patients. For each patient the current clinical pathway is presented.

Mr B

- Age 66 years
- Diagnosed with Diabetes Type II in 2000
- Controlled on diet
- Monitored in the surgery every 6 months
- Family history of heart disease.
- Angioplasty 1999 for 1 stenosed vessel
- High cholesterol
- Uncontrolled sugar levels HbA1c 7.5 March 2010
- Hypertension

Case history

Mr B is 66 and was diagnosed with Type II Diabetes Mellitus in 2000 after a routine occupational health check carried out through his employer. Mr B attends a 6-monthly Diabetic clinic at the health centre and had been controlling his diabetes with his diet. However, his last HbA1c test in March 2010 indicated uncontrolled blood sugars as his HbA1c had increased to 7.5%.

Mr B also has a family history of heart disease and had an Angioplasty in 1999 for a stenosed vessel. He also suffers from high cholesterol and hypertension, both of which are being treated with medication.

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[4] The national Quality and Outcomes Framework (QOF) was introduced as part of the new General Medical Services (GMS) contract on 1 April 2004. Participation by practices in the QOF is voluntary, though participation rates are very high, with most Personal Medical Services (PMS) practices also taking part. Background can be found on the Department of Health website: www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/QOF/index.htm

Presentation:

- Glucose in his urine September 1999
- GP requested blood tests (glucose and HbA1c)
- HbA1c 6.8%
- Given diet advice
- Pt controlling blood sugar with diet.

Diagnosis:

- Diagnosed Diabetic Type II in 2000
- HbA1c 6.7 %
- Fasting Glucose 6.0mmol/l
- Between 2001 -2007 HbA1c below 7%
- Fasting blood sugars showed a slight increase.

Risk factors:

- Consistently High Cholesterol
- Smoking
- Diabetes
- Hypertension.

Co-Morbidities:

Heart Disease

- January 1999 developed chest pain at rest
- Angiography showed 1 stenosed vessel
- Percutaneous transluminal balloon angioplasty of 1 coronary artery
- Stopped smoking in June 1999 reducing his risk of further cardiac episodes.

Hypertension

- Jan 2007 elevated BP 170/90 Bisoprolol 7.5mg OD (Beta blocker)
- March 2007 BP elevated again 160/75
- Pt monitoring BP at home
- BP elevated in January 2008
- Ace inhibitor started 2.5mg (Ramipril)
- Increased to 5mg in Feb
- Nose bleeds 2009 Cauterised
- Increased Ramipril April 2009 to 7.5 mg.

High Cholesterol

- Early July 1999 Cholesterol level 6.7mmol/l
- Commenced on Simvastatin 10mg OD
- Repeated cholesterol level at 1 month 4.6mmol/l
- Elevated triglycerides even though cholesterol level within normal range.

Interview session

Mr B was accompanied to the session by his wife. The session was opened by asking Mr B how he felt his diabetes management was currently being delivered and if there was anything else that might help him and his family cope better and differently.

"So far I have been diet controlled and as such it is down to me to manage this. However, when it [blood sugar] rises, I see it very much up to the doctors to tell me what needs to be done".

"After 10 years of denying myself an ice cream, and chocolates and things like that, I do tend now to have a bit of chocolate and ice cream. But I do not go mad on it, maybe a small piece of chocolate once per week".

"The wife does nag me, and sometimes when I am at my daughter's, she buys buns or donuts" They do know that he should not be eating, but "I do it anyway".

"I do not have much time left on earth and so I do have one or two things that I like", but does not feel that he goes mad. "I try to keep to a good diet, I like fruit as well, but that has sugars in as well", does not always stick to a small portion size.

When asked about his blood sugar levels, "Yes they have just gone up, I had a test (HbA1c) a few months ago and it went up from 7 to 7.5. I saw one of the doctors to review the results and was told that if it continues to increase something would have to be done".

Mr B relies on the 6-monthly tests to gauge his blood sugar levels, although does not fully understand what they represent. "Yes if I did not trust it then I would not come down [to the clinic], but if I did not have the tests, then I would not know there was a problem". Mr B discovered he had Diabetes during a routine occupational health check carried out through his then employer The London Underground (a transport network in London) where he worked for 37 years. "I had no other symptoms, which is why I could not understand it when it was first diagnosed it… I was very surprised".

Mr B stated that he had never done any Blood Glucose testing at home previously and relied on the 6-monthly tests in the Diabetic Clinic held at the health centre.

When asked if he finds being told to do something on a daily basis a bit oppressive, Mr B said "Yes, but if I am told I have got to then I will. I was told to pack up smoking, so I stopped smoking. So if I am told to cut down then I will cut down – but will not cut everything out completely".

When asked if there was a way of knowing what the blood sugars were all of the time, would he see any value in that for him and his family? "I would find that interesting as I say I like a bit of chocolate and fruit and if it will go up because I have eaten the chocolate, I would then stay off the chocolate to see if the values would come down. So it would be interesting to see what affect the chocolate is having". When asked if this would give him second thoughts about eating the chocolate and donuts. "Yes it might – it would be a factor"

Both Mr and Mrs B thought that it would be interesting to see some sort of graphical representation of his blood sugar measurements that he could relate to his diet, although again reaffirmed that even if he saw this he might still have the chocolate but that he would be more informed and that it would be "his choice".

Mrs B was then asked about what affect Mr B's diabetes has had on the other members of the family. "He has coped well and does not complain; you would not really know that he has this problem. I am aware of his diet and on the whole he eats fairly well but he stopped smoking which can make you eat more, but he eats fruit"

Both Mr B and Mrs B do not always know what is the "right" thing to eat, so they would find it interesting to see what affect the different foods would have on Mr B's blood sugar levels to help him make better choices. Mr B would not mind wearing a patch as long as it did not interfere with his daily routine.

Conclusion

Mr B copes with a variety of co-morbidities, some of which pose a more immediate risk to his health.

Mr B's story illustrates what it is like to be a diabetic who is asymptomatic, with heart disease and hypertension. It demonstrates the importance of monitoring someone who has no symptoms as clinicians normally respond to symptoms.

It further illustrates how the whole family is affected by the disease. And that they play a key role to help cope and influence the management of the disease.

Mr B has an overwhelming want to be as "normal" as possible and live as "normal" a life as possible.

Both Mr B and his wife believe that they would find monitoring supportive of life/diet changes.

Management

- 6-monthly monitoring in the Diabetic Clinic
- Encouraged to lose weight BMI 27
- Raised urea level in 2006
- HbA1c steadily increasing
- March 2010 saw an increase in HbA1c 7.5%
- Plasma glucose 7.1mmol/l
- If glucose still raised in 6 months to start Hypoglycaemics.

Clinical pathway
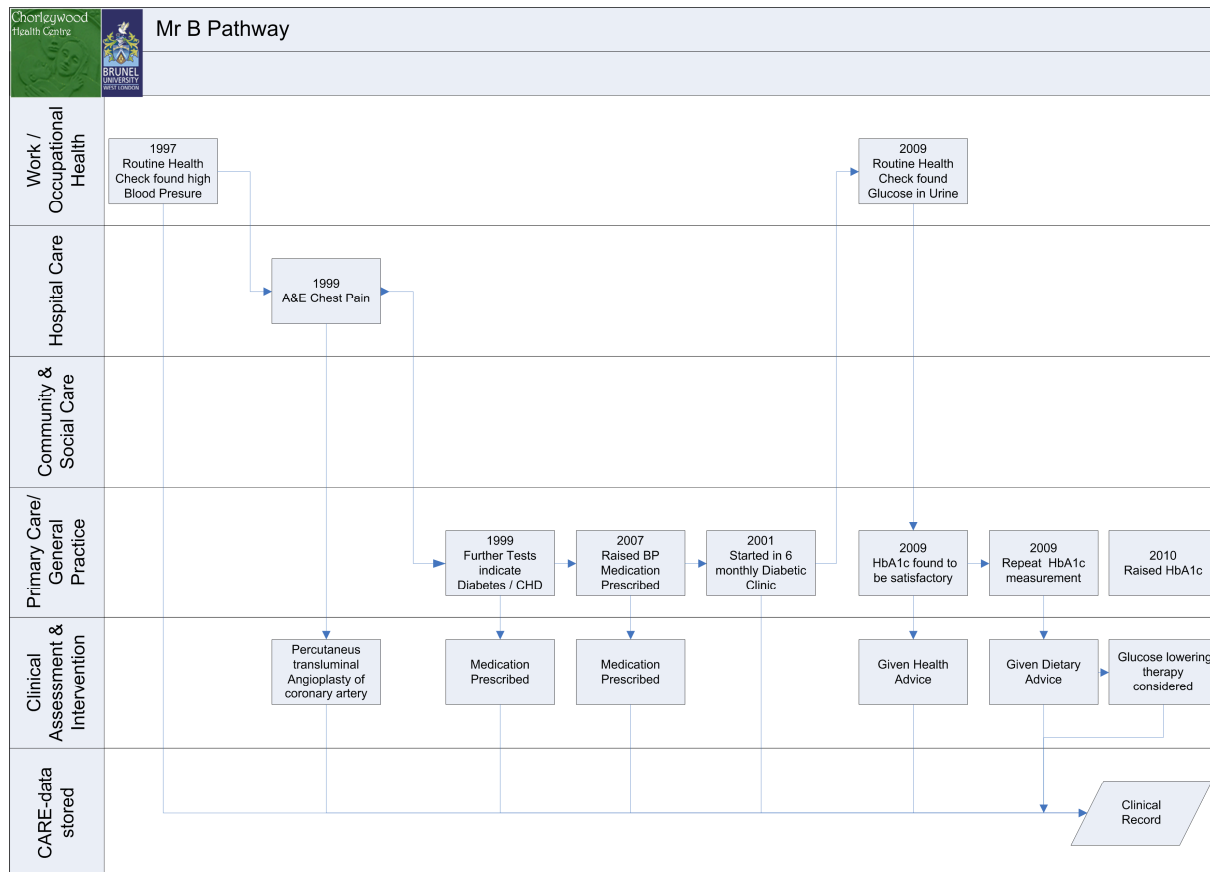
Figure 4 Clinical pathway for Mr B

Mrs S

- Age 78
- Diagnosed with Diabetes Type II in 2006
- Co-morbidities – asthma, IHD, RA and heart failure
- Commenced on metformin but stopped due to side effects
- Switched to Gliclazide until 2009 – symptoms of angina again and became symptomatic (thrush, frequency of urine)
- Angioplasty – stents x2 to heart in 2009 – restarted on metformin MR
- HbA1c not reduced therefore started on basal insulin
- Currently trying to get acceptable regime for Mrs S as she has other co-morbidities. She also cares for her husband
- Becoming quite depressed about the whole situation

Case history

Mrs S is 78 and was diagnosed with Type II diabetes in 2006. Her blood sugars were found to be uncontrolled during a previous remote patient monitoring study for Heart Failure. At the time she was put on medication which managed the sugar levels for a while. In 2009 Mrs S started to become symptomatic (thrush, frequency of passing urine). Initially she was on a twice daily regime, but there were some misunderstandings around dosages and she has recently had to increase to three times daily. Blood sugar levels now are running at around 16-28 which are far too high and possibly due to a recent viral illness. Another key priority in gaining control of her blood sugar levels is to enable her to undergo a cataract operation.

Mrs S has had two recent heart operations and also has a number of other co-morbidities including asthma, ischaemic heart disease, rheumatoid arthritis, heart failure and depression. She is also a carer for her husband who is developing a senile dementia and with whom she has a volatile and sometimes abusive relationship.

Presentation:

- Originally diagnosed by blood tests done whilst part of the RMP for heart failure
- Not overtly symptomatic but several incidences of thrush and an increased incidence of UTI and LRTI
- Starting blood glucose levels were not too high as discovered at an early stage – started on metformin

Diagnosis:

- Type II diabetes in 2006

Risk factors:

- Carer for husband – relationship volatile
- Anxiety/depression – not on any anti-depressants at the moment
- Has supportive daughter but she is busy with her own life
- All this impacts on best diabetes care – multiple blood tests – insulin injections

Co-Morbidities:

Essential Hypertension

- Diagnosed during routine surgery appointments
- Started on Amlodipine in June 1996 – stopped 09/96
- Changed to Hydrochlorothiazide 09/1996 – stopped 11/2001
- Changed to Bendroflumethiazide 11/2001 – stopped 07/2003
- Changed to Doxazosin 11/2001 – stopped 07/2007
- Ramipril commenced in 2006 (after diagnosis of diabetes) – switched to Losartan due to side effects (cough)
- Felodipine introduced in June 2007

Asthma

- Diagnosed in the surgery by GP – on inhaler therapy
- Recently become more COPD than asthma
- Anticholinergics introduced 2008 but concordance with inhalers is a bit erratic

Ischaemic heart disease

- Chest pain in August 2000 – went to A&E in ambulance – admitted and diagnosed with angina – started on treatment for angina and put on statins and aspirin.
- Followed up in OPD for exercise tests and angiograms
- Angioplasty to femoral and coronary arteries

Heart failure

- Initially suspected by GP in 2003 – started Furosemide then discontinued as felt to be more asthma.
- 2004 suspected again due to fluid retention – confirmed in 2005 by BNP

Hyperlipidaemia

- Discovered while in-hospital for chest pain

Interview Session

The session was started with asking Mrs S about some of the current problems she is experiencing. "I feel old before my time, I want to be able to get on with all the things that I want to get on with. I feel tired and I feel I cannot be bothered and have to force myself to do things… I do not feel like I did two or three years ago". Mrs S feels that physically she should be feeling better than she does. So illness is a very big factor affecting the quality of her life.

When asked about how it affects her daughter, Mrs S said that while her daughter will drive her around to appointments and places as well as encourage her to do things for herself as well as for her husband; her daughter has her own life and she does not want to be a burden on her.

When asked what she thinks that the health centre could do that would be useful, she answered, "Getting the blood sugars down so that I do not have to preoccupy myself… whether I need to be put on a diet I do not know. I do not know what to do; I control my diet, eat at regular times and do not eat lots of sweets".

Mrs S feels a sense of frustration "I feel like I am getting nowhere and this has been going on since December, when I first saw a nurse and it is just going on and on".

It was acknowledged by the clinical team that it was perhaps taking longer than it should to help Mrs S gain control over her blood sugar levels.

Mrs S currently monitors her blood sugar three times per day or more if she feels unwell. She keeps a record of these measurements and brings them to her visits to the health centre for review. She keeps all of these for her own records as well. When asked if she can predict her own blood sugar levels, she said that she sometimes takes a reading when she feels hungry, but this does not usually correspond with a high blood sugar reading.

The clinical team discussed how they have been using the records kept by Mrs S to help in their clinical decision making in increasing Mrs S insulin doses. However, Dr Jones said, "We need to unplug inhibitions in care. If you are not experienced in using insulin, you are fearful of the consequences of acting, but you need the evidence to support the decisions. We [clinicians] need access to her [Mrs S] blood sugar to see the pattern, so that we know where the blood sugar is and what dosage is right. Then we can push the insulin up as much as we need to get the right result".

Finally Mrs S was asked if she would mind wearing a small patch that would stay on all of the time, but that would not affect her daily business. Mrs S said that she would not mind.

Conclusion

Mrs. S copes with a number of other co-morbidities.

Is feeling unhappy, lonely and depressed.

Is worried about Sugar Control and is upset and frustrated by more than 4 months of uncertainty about how to control it.

Is fed up of feeling unwell and just wants to be normal, "I want to be well".

Has to juggle caring for her husband and the problems in their marriage as well as dealing with the diabetes and other illnesses.

Is not particularly interested in seeing data/feedback from monitoring but does not mind monitoring as it might help.

The clinical team needs to see the blood sugar information in order to titrate the insulin dosages to optimum level safely.

Management

- For 6-monthly monitoring in the Diabetic Clinic
- Diet and lifestyle advice at every visit
- Commenced metformin but stopped after 3 weeks due to gastric side effects
- Gliclazide commenced – all fairly stable until 2009
- Metformin re-introduced (MR formulation)
- HbA1c still high – insulin commenced 11/09

Clinical pathway

Mrs S Pathway1 Type 2 Diabetes

Work / Occupational Health	
Hospital Care	2000 Ischaemic Heart Disease → 2000 Hyperlipidaemia → 2000 Angioplasty
Community & Social Care	
Primary Care/ General Practice	1996 Essential Hypertension 2000 Asthma 2003 Suspected Heart Failure → 2005 Suspected Heart Failure
Clinical Assessment & Intervention	Medication Inhaler Therapy Medication Exercise Tests Angiograms Medication Confirmed with BNP test
CARE-data stored	Clinical Record

Mrs S Pathway2 Type 2 Diabetes

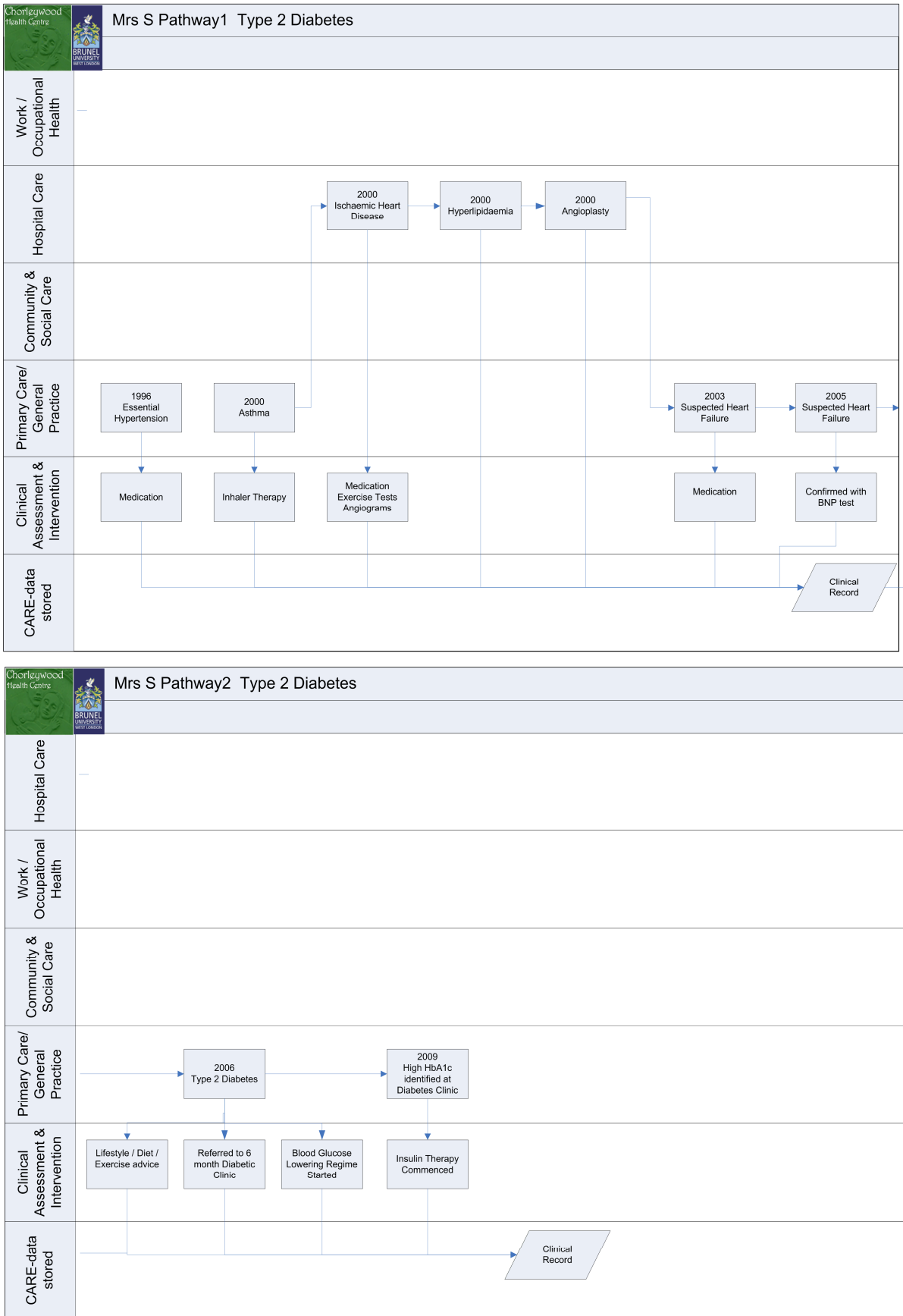|	
Hospital Care	
Work / Occupational Health	
Community & Social Care	
Primary Care/ General Practice	2006 Type 2 Diabetes → 2009 High HbA1c identified at Diabetes Clinic
Clinical Assessment & Intervention	Lifestyle / Diet / Exercise advice Referred to 6 month Diabetic Clinic Blood Glucose Lowering Regime Started Insulin Therapy Commenced
CARE-data stored	Clinical Record

Figure 5 Clinical pathway for Mrs S

Mrs B

- Age 39
- Diagnosed with Type I DM in 1975 aged 5
- Has Ehlers-Danlos syndrome – a connective tissue disorder – diagnosed age 4
- Acquired hypothyroidism in 1993 age 23
- 2 children born by elective Caesarean section following 5 miscarriages
- Recent echocardiogram and exercise testing have demonstrated some changes in the heart
- Is known to have background retinopathy
- HbA1c is 6.1% - recent blood tests show normal renal function
- On basal bolus insulin regimen

History

Mrs B is aged 39 and has been treated at the health centre since she was a young child. She was diagnosed with Type I Diabetes when she was 5 years old. She was also diagnosed with Ehlers-Danlos syndrome, a connective tissue disorder, which is hereditary when she was 4 years old. The condition means that the skin is very loose and is very delicate. This caused a lot of problems when she was younger and still does. She was then diagnosed with hyperthyroidism in 1993. It is not uncommon for someone with one autoimmune condition to develop another one. She has two children born by elective caesarean but had miscarried on five previous occasions. A recent echocardiogram and exercise test have demonstrated some changes in the heart which a cardiologist is currently investigating. Mrs B also has a background of retinopathy but has had no laser treatment yet and they are just keeping an eye on it. She is overweight.

Mrs S is on a basal bolus insulin regime and is currently controlling her blood sugars very well; her last HbA1c was 6.5%. Recent tests show that her renal function is normal.

Presentation:

- Presented age 5 at hospital following episode of confusion and bed wetting at night.
- Found High Blood sugars in Urine and diagnosed with Type I Diabetes
- Often seen in surgeries due to EDS
- Overweight from an early age – still a problem

Diagnosis:

- Diagnosed with Type I Diabetes when she was 5 years old
- Also diagnosed with Ehlers-Danlos syndrome
- Diagnosed with hyperthyroidism in 1993

Risk factors:

- Impact of ill health from childhood
- Weight management issues from an early age
- Problems maintaining a healthy pregnancy – concerns about inherited EDS
- Depression
- Recent worries about cardiac symptoms

Co-Morbidities:

Ehler-Danlos syndrome

- Connective tissue disorder – which delays healing
- Allergic to plasters and wound products

Acquired hypothyroidism

- An autoimmune condition
- Picked up on a routine blood test

Depression

- Came on shortly after the birth and was treated as post natal depression initially
- Has been treated intermittently
- Declined anti-depressants
- Referred to physiologist

Interview Session

The session was started by asking Mrs B what could be done differently in relation to her diabetes care. "The monitoring is a pain, I have very little time with the young children, so I tend not to do it and judge my body". Mrs B feels that as she has had diabetes for a long time she has been able to judge when there might be a problem. "The only times, I do tend to monitor, apart from when I was pregnant…., is either when I do not feel very well, when I feel the start of a hypo coming on or sometime when I wake up in the middle of the night and not sure why". Most of Mrs B's hypos come on at night.

In total Mrs B might monitor a total of 4 times per week. She feels that to date she has been quite successful as her HbA1c's have been within limits. However she is aware that she does not see her rise and falls especially around meal times. "If I am going to have a big meal, I will do an extra injection but I do not know if I am overcompensating or not doing enough". As such, she feels it would be very useful to have that information without having to go find a glucometer.

This in itself can be quite challenging with two young children around as she will put it somewhere safe and out of reach but then sometimes forgets where she has put it. "It ends up with a frantic hunt and a shout at everybody and then I cannot find the syringe and end up using a normal syringe which hurts". So there is an underlying need to make the process simpler to manage.

Mrs B was asked if the children were involved in her diabetes care at all. "Yes they are very interested, I encourage it and get them to ask questions…. they both know that if I say to them to go to the fridge and get my green insulin they are quite capable of going and getting it". Her daughter has even used a pen to simulate injecting herself.

Mrs B would like "something that is easier and could fit into a smaller bag". Mrs B find's it difficult to manage carrying around all of the various syringes and blood glucometer etc. "That is a part of the problem, feeling as though you are ill when it is just diabetes…. When you get to the airport and you have syringes and the glucometer and that's a pain".

Mrs B also mentioned that in the past and especially during her pregnancy she has been made to feel that any rise in her blood sugar over a certain level was "her fault".

When asked if she would be willing to have a small patch placed on the surface of her skin somewhere which would measure the blood sugar levels, Mrs B pointed out that because of her skin condition, she is allergic to plastic and waterproof material. So that any device would need to be made of a material that she was not allergic too.

Mrs B was also asked that given she has successfully managed her condition to date but only monitoring a few times weekly and trusting in her own instincts, whether she would change her lifestyle based on any feedback from a new device. "I think I would, I am 40 on Monday and am having a bit of a mid-life crisis and have not been feeling well the last few months, so if I knew I think it would help. And like when I was pregnant, it would give me the oomph [motivation], to stop me eating as many mars bars. Obviously having the background of retinopathy as well, I really need to start monitoring more".

Finally, Mrs B was asked if she had any privacy concerns over data being transmitted from the patch to a server, or clinical location and she said that she did not.

Conclusion

Wants something that will make her life easier and that does not make her feel that she is unwell through having to carry around so much stuff.

Is very knowledgeable about her conditions and for the most part understands how to manage them.

Only currently does blood glucose monitoring when she feels unwell or as the start of a hypo.

Her family are very supportive in her management of her diabetes.

Would welcome monitoring and feedback in order to gain more information on the variances in her blood sugar.

Her condition means that she is highly allergic to dressings and plasters.

Management

- As Type I she has been on insulin from diagnosis
- Currently uses Novo rapid to allow for greater freedom
- 6-monthly monitoring in the Diabetic Clinic
- Lifestyle advice
- Weight loss programme.
- Regular Blood pressure checks
- Exercise
- Diabetes management – currently very well controlled – HbA1c 6.1%
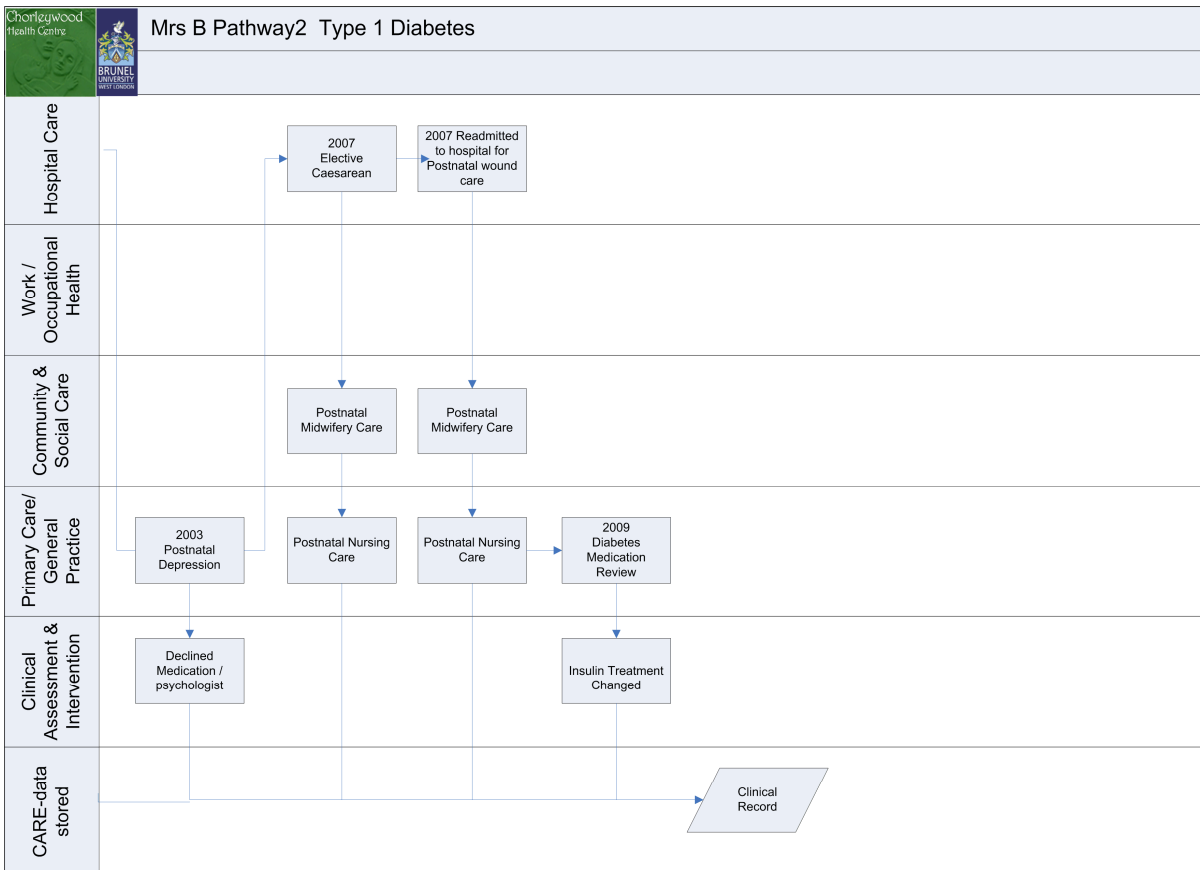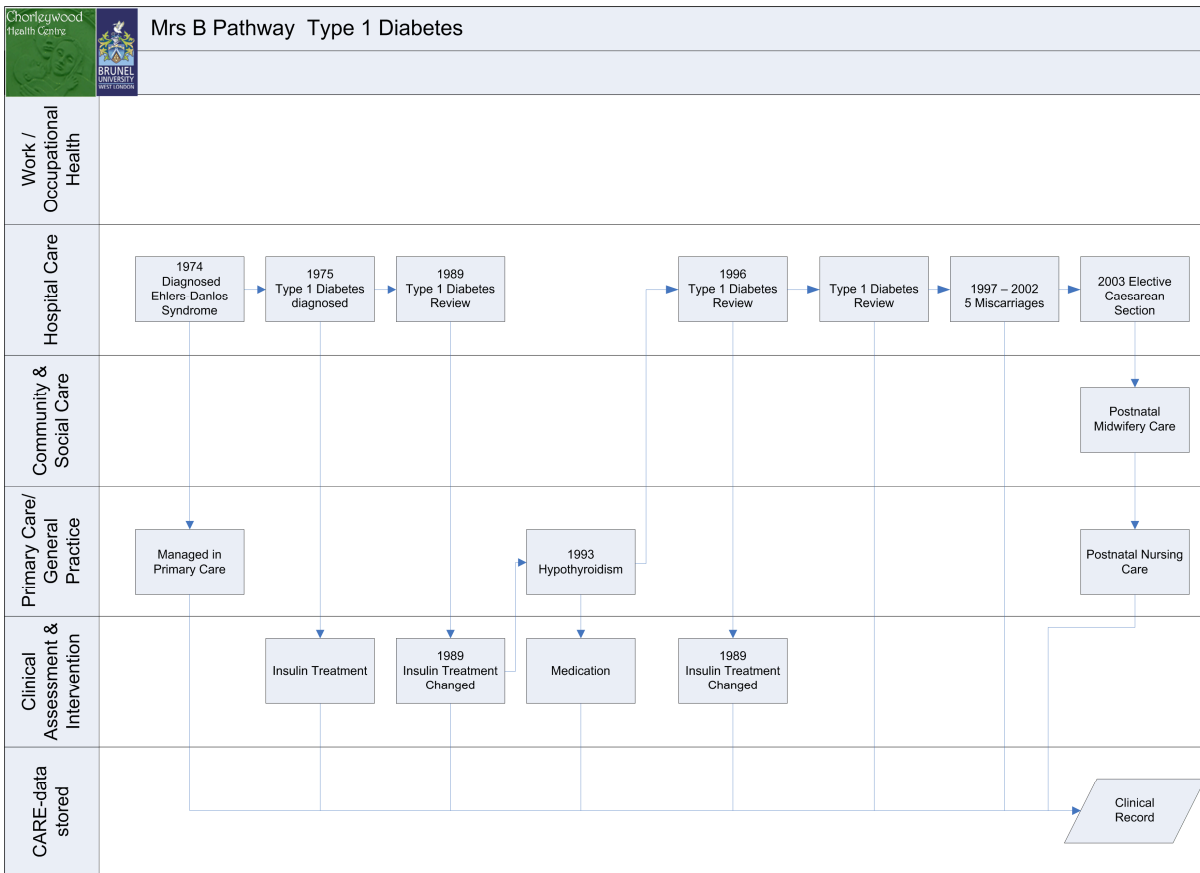- Renal function normal

Clinical pathway

Figure 6 Clinical pathway for Mrs B

Mr N

- Age 56 years
- Impaired glucose tolerance.
- Increased plasma glucose levels in February 2010.
- Essential hypertension.
- Overweight.
- Alcohol intake increased.
- Gout.
- Needs lifestyle changes.
- Abnormal liver function tests.

History

Mr N who is aged 56 presented earlier this year with raised blood pressure; he has a history of hypertension. On this visit he was found to have an impaired glucose tolerance suggesting pre-diabetes. He has a number of co-morbidities and is on medication for hypertension and high cholesterol. He is overweight BMI 36 and suffers from gout. There is a family history of heart disease.

He is a busy landlord of a pub which is stressful and he works long hours. His condition requires lifestyle changes, which need to be monitored to ensure that they are making a difference.

Presentation:

- Raised Blood Pressure
- Raised Gamma GT level
- GP requested blood tests.
- Plasma fasting glucose 7.3mmol/l

Diagnosis:

- Impaired glucose tolerance suggesting pre-diabetes

Risk factors:

- Consistently high cholesterol
- Smoking
- Diabetes
- Hypertension
- Family history of heart disease

Co-Morbidities:

Hypertension

- December 2007 BP elevated.
- Diet and lifestyle advice given
- Smoking cessation advice given.
- January 2010 BP elevated again
- Commenced on Amlodipine

High Cholesterol

- 2007 Cholesterol level 6.6mmol/l
- Commenced on Simvastatin 20mg OD
- 2010 repeat bloods
- Cholesterol reduced to 4.6mmol/l

Interview Session

The session began by asking Mr N about the lifestyle changes that were required. "Easier said than done, I have had problems with my knees, I had two operations and so I was not very mobile. I do run a pub and we do 60-70 hours per week so I do not have a lot of time to do other things. They say I should do exercise and things like that, but it is too hard to fit in to the day". Mr N also has a problem controlling his intake of food. Mr N is a self-confessed binger who finds it difficult to restrict himself to one crisp or one biscuit, and "because food is accessible all the time, I do a lot of picking".

While Mr N would like to get back to the golf course, the problems with his knees has meant that he has not been able to.

When asked what might help him with the lifestyle changes, Mr N talked about monitoring. "I do try to weigh myself everyday". And while he did buy himself a blood pressure monitor he has not really used it saying that he "would like something simpler, something that you could perhaps just put a finger on. Sometimes you put it on and it is not quite in the right place or it is too tight or too loose". When asked about measuring blood sugar "I have not thought about measuring blood sugar before as I have only recently discovered the problem… Something simple".

Mr N has recently had a liver function test that had come back not as it should be, this has resulted in him cutting down his alcohol intake by 50%. He has also given up smoking which has not helped with his trying to lose weight. Also a friend of his has just undergone major heart surgery which has also shocked him.

Mr N was asked whether healthy lifestyle messages either on TV or at the health centre made any difference to him. He suggested that it was not until he had the problem, hypertension, that he took any notice of them.

It was suggested that perhaps Mr N still saw himself as still being in his 30's and Mr N agreed. He said that while he did try to cut back, there was a quality of life issue. "you need to balance it, I have gout and someone gave me a diet sheet and said that all I could eat was non oily fish and skinned chicken, well I do not eat fish and while I do like chicken…." His wife also has tried to provide him with a better diet but it has not worked. "Ok so I can go on these diets and I can live another 10 years longer, but I will be miserable for the whole time".

When asked that if he was monitored on a daily basis for a few weeks to see what his blood sugar levels were and he was then shown how these go up and down because of what he was doing, he said that this might help.

Conclusion

He is coping with a number of other co-morbidities.

His condition requires significant lifestyle changes, which he is finding hard to cope with.

Quality of life is very important to him and he does not want to give up everything that he enjoys.

He might accept monitoring to support habit change.

Management

- 6-monthly monitoring in the Diabetic Clinic
- Reduce alcohol intake
- No smoking
- Weight loss programme.
- Reduce dietary intake
- Regular Blood pressure checks
- Exercise

Clinical Pathway
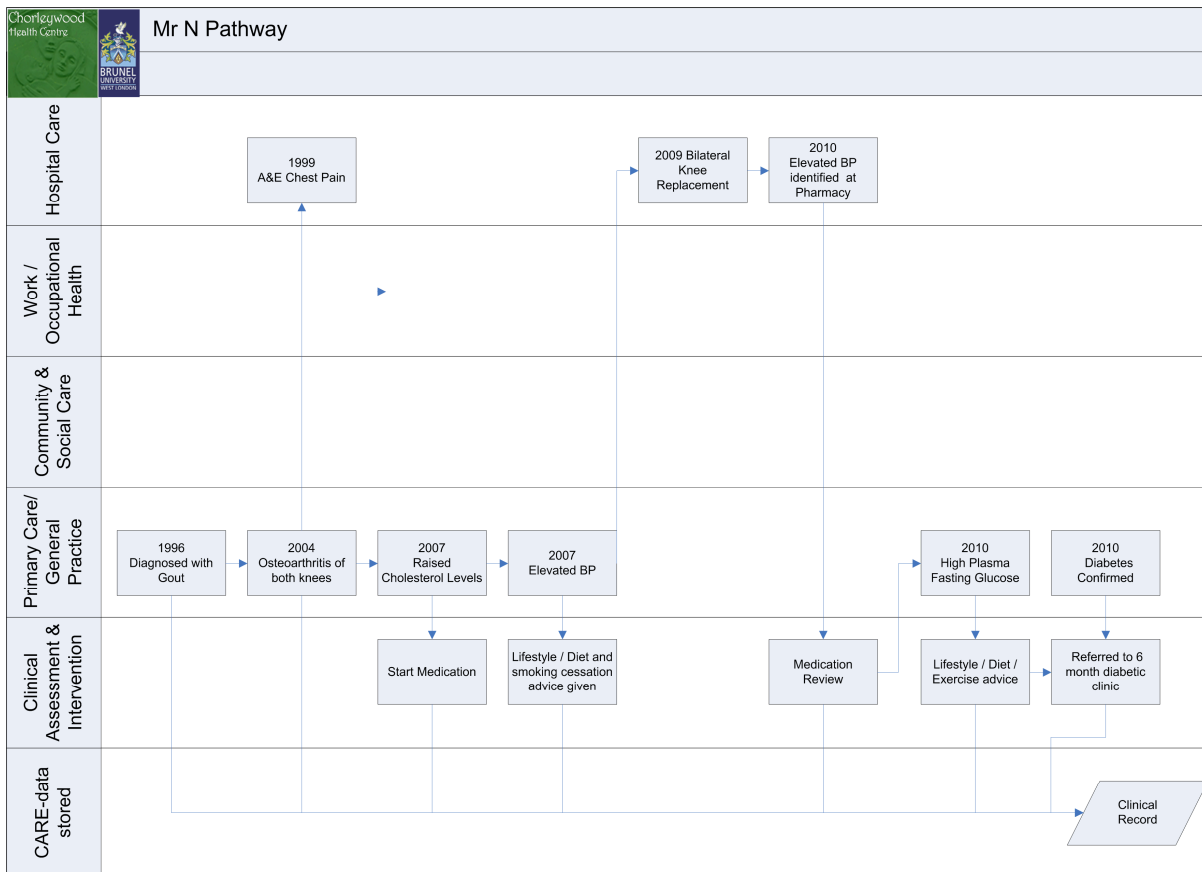

Figure 7 Clinical pathway for Mr N

Mr M

- Age 69 – Asian
- Complex history of IHD, MI x 2, CABG x 2
- Also has chronic kidney disease
- Diagnosed with Diabetes Type II in 2006 – commenced on metformin
- Gliclazide added in 2008
- Recent cardiac event whilst in Kenya – metformin stopped
- Recent blood tests show worsening renal function – unable to stay on metformin
- HbA1c increasing – now 7.5%
- What options now? High risk patient – increasing BMI (30)

History

Mr M is a 69 year old man from an Asian background; he has a complex history of ischaemic heart disease and has had two heart attacks. He has had two coronary heart operations. A few years ago it was noticed that his kidney function was not as good as it should be and he was diagnosed with Type II Diabetes in 2006. He was started on Metformin and his diabetes was relatively well controlled. During a recent trip to Kenya he suffered from chest pain and was admitted to hospital with a cardiac event. While in hospital they stopped his Metformin medication. Tests on his return indicate that his renal function has slightly changed again which means that Metformin cannot be used now for him because it could cause more problems with his kidneys. His HbA1c is going up and there is a need to do something and the clinical team are currently looking at the options.

His unstable angina probably means that another angiogram will be required to assess what more needs to be done to the coronary tree and gaining better control of his blood sugars will help impede the progress of the vascular disease.

Presentation:

- Diagnosed as a result of tests done while being screened for other illnesses
- High risk due to several factors – Ethnicity, raised BMI, lifestyle issues

Diagnosis:

- Impaired glucose tolerance suggesting pre-diabetes

Risk factors:

- Asian – controversial but overwhelming evidence suggests that risk of diabetes is 3-4 times more common than that in Caucasians
- Frequent traveller – recent heart event was in Kenya
- Business man who until recently was head of his family – now relying on wife more and more – she also cares for her elderly mother
- Worried about how diabetes will impact on his life in the future
- Eye problems – glaucoma – retinal screening abnormal

Co-Morbidities:

Heart Disease

- 1982 – Acute Myocardial Infarction - treated in hospital – old paper notes don't give much information
- 1993 – Coronary artery bypass grafts
- Developed chest pains in March – had an exercise stress test done here in surgery which was positive – sent to cardiologist and CABG done end of April 1993 in hospital
- 2000 – Acute Myocardial Infarction - admitted to hospital
- 2000 – Angioplasty to coronary arteries - Done in hospital

Impaired renal function

- In 1997 blood tests reveal that renal function has deteriorated and referred to kidney specialist – restarted on beta-blocker (Atenolol)
- 2002 – Chronic kidney disease stage 1 – already knew he had reduced renal function but we started to classify kidney disease into stages at this time (National Guidance)
- 2009 – Chronic kidney disease stage 3 – showed up on blood tests done by surgery

Eye disease

- Referred for retinal screening at diagnosis of diabetes (2006) – seen at optician and early signs of cataracts noted – also raised intra-ocular pressure. This was noted to be higher a few weeks later at the optician so a referral to secondary care ophthalmologist done. Diagnosis of glaucoma and treatment for this started in April 2006.

Interview Session

Mrs M was also present at the session. The session began with a question about what were the issues for Mr M in regard to his diabetes. Both Mr and Mrs M felt that as nothing "adverse" had happened yet that they did not really know. Mr M was concerned that Diabetes was a "killer" and that now his blood sugar levels were not so well controlled, he was questioning how it was going to affect him from now on.

When asked what the clinical team could do to help him manage his care Mr M replied "you should tell me". It was suggested to Mr M that he approaches his clinicians as if he were making a deal, that he negotiates his care – what is that you are going to do for me. Both Mr & Mrs M agreed that they expect the clinicians to tell them what they should do. Mrs M "we trust the doctors, If we did not we would not have stayed here this long".

As Mr M has a back problem he is also unable to do much exercise, Mrs M also said that while he has quite a good diet, Asian food is quite high in carbohydrates. They both are very uncertain about what they should or could do to help manage the disease.

When it was suggested that the next step in the care of his diabetes might involve going onto insulin therapy, Mr M was particularly adamant that he did not want to do this. Mrs M said that he was concerned about the injections but that she was sure that Mr M would follow the advice as a last resort.

Mr M has recently purchased a Blood Glucose monitor, but has only used it once. He is unsure of how often and at what time he should take a measurement. When asked that if as a consequence of measuring blood glucose and gathering data about blood sugar levels consistently over a short period of time indicated that

insulin therapy was the only option would he firstly agree to the monitoring and secondly agree to the results and move onto the insulin therapy, Mr M agreed that he would as "he would have the information".

Conclusion

There is a situation of real uncertainty.

There is a threat from his heart disease which requires further investigations.

The diabetes is becoming more of an issue and the clinical team are actively trying to find ways to resolve this.

Mr M and the family need to know where they are at and are surrounded by uncertainty.

Technology could help remove some of these uncertainties and provide the information that is needed.

Management

- For 6-monthly monitoring in the Diabetic Clinic
- Started with metformin
- Intolerant to metformin – changed to Gliclazide
- Restarted metformin
- Metformin stopped – CVE in Kenya
- Recent blood tests indicate worsening renal function
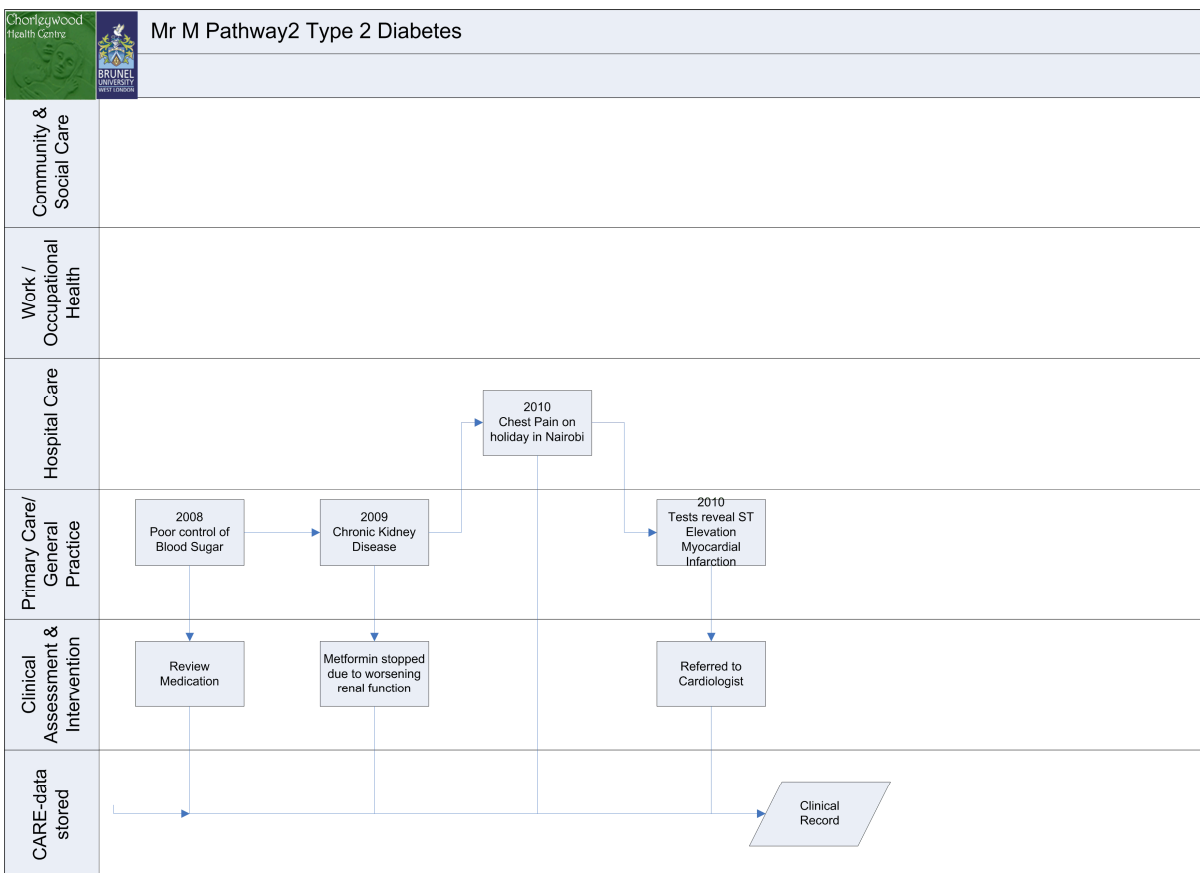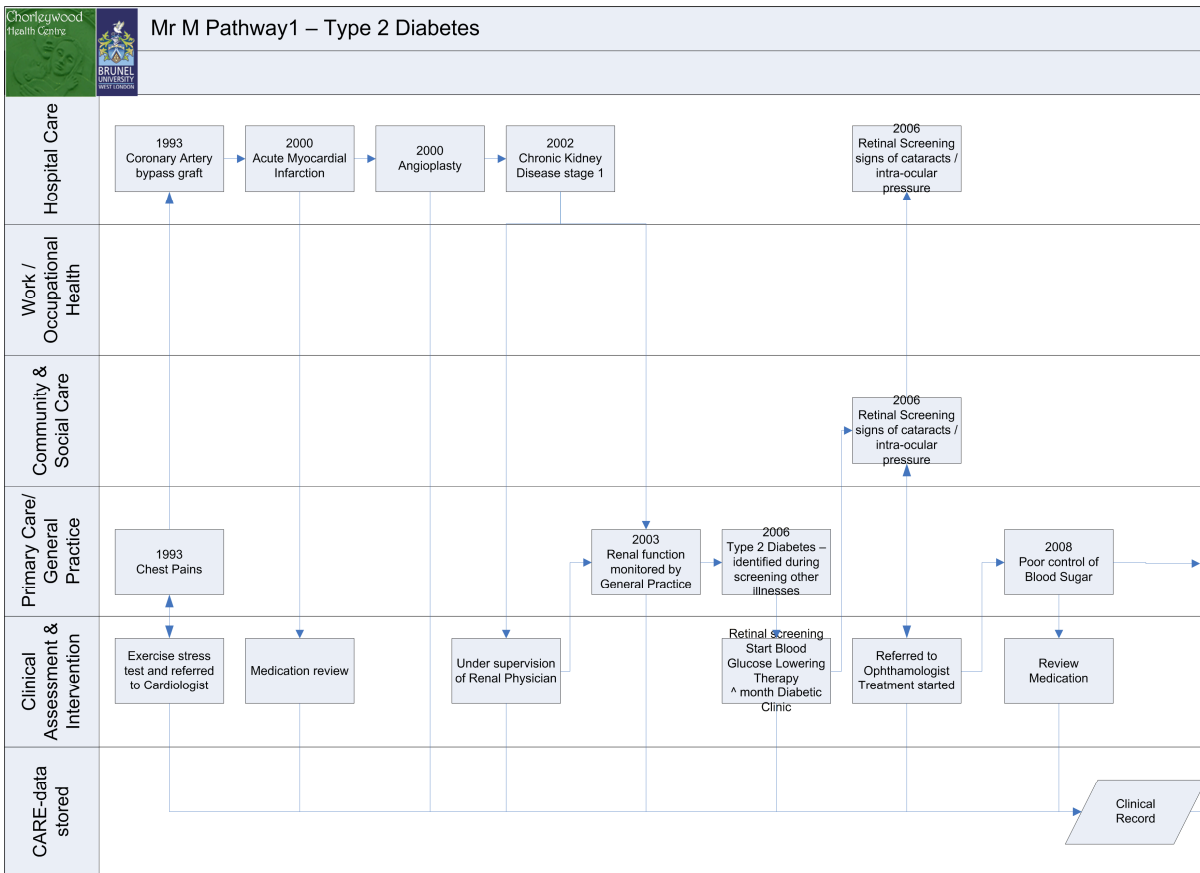- Awaiting referral and management from cardiologists

Clinical pathway

Mr M Pathway1 – Type 2 Diabetes

	Hospital Care	Work / Occupational Health	Community & Social Care	Primary Care/ General Practice	Clinical Assessment & Intervention	CARE-data stored

Hospital Care
- 1993 Coronary Artery bypass graft
- 2000 Acute Myocardial Infarction
- 2000 Angioplasty
- 2002 Chronic Kidney Disease stage 1
- 2006 Retinal Screening signs of cataracts / intra-ocular pressure

Community & Social Care
- 2006 Retinal Screening signs of cataracts / intra-ocular pressure

Primary Care/ General Practice
- 1993 Chest Pains
- 2003 Renal function monitored by General Practice
- 2006 Type 2 Diabetes – identified during screening other illnesses
- 2008 Poor control of Blood Sugar

Clinical Assessment & Intervention
- Exercise stress test and referred to Cardiologist
- Medication review
- Under supervision of Renal Physician
- Retinal screening Start Blood Glucose Lowering Therapy ^ month Diabetic Clinic
- Referred to Ophthamologist Treatment started
- Review Medication

CARE-data stored
- Clinical Record

Mr M Pathway2 Type 2 Diabetes

Community & Social Care

Work / Occupational Health

Hospital Care
- 2010 Chest Pain on holiday in Nairobi

Primary Care/ General Practice
- 2008 Poor control of Blood Sugar
- 2009 Chronic Kidney Disease
- 2010 Tests reveal ST Elevation Myocardial Infarction

Clinical Assessment & Intervention
- Review Medication
- Metformin stopped due to worsening renal function
- Referred to Cardiologist

CARE-data stored
- Clinical Record

Figure 8 Clinical pathway for Mr N

4.4   Description of Existing Workflows

The Map of Medicine[5] provides locally relevant evidence-based, practice-informed pathways that support clinicians in providing best practice. The Map of Medicine covers over 350 clinical topics. For Diabetes, these pathways include:

- Management of Diabetes
- Insulin Therapy
- Suspected Diabetes in Adults

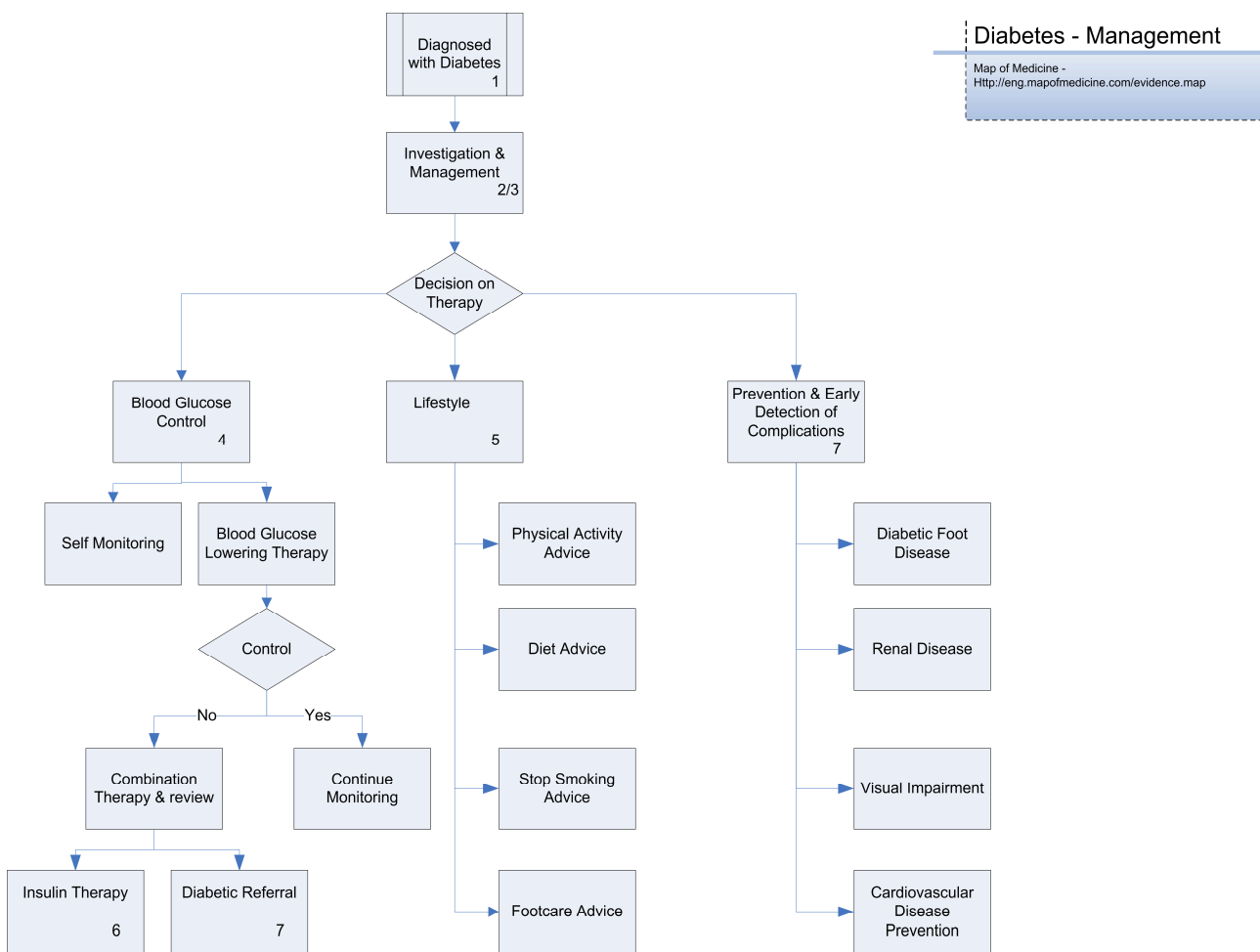As the pathways are iterative, for example the management of diabetes would be repeated at each 6-monthly interval at the diabetic clinics.

Figure 9 Existing workflow for management of diabetes

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[5] The Map of Medicine is a synthesis of best available research evidence and a best evidence clinical guideline. It is a one stop clinical resource for clinical decision making, continuing professional development and medical education. http://www.mapofmedicine.com/

4.5   Description of the Steps in the Existing Workflow

1	Start of the workflow
Staff:	Physician, nurse

Patients are identified as having diabetes; some patients have presented with symptoms or have had screening which has confirmed that they have diabetes. Patients are entered on to an electronic register and are then invited to attend a Diabetic Clinic at the health centre for a review every six months

Clinical Presentation (Source: Map of Medicine)

Diabetes can present as a hyperglycaemic emergency, symptomatically or be discovered during a routine health check:

- symptoms of diabetes:
- symptoms of hyperglycaemia:
- polydipsia
- polyuria
- blurred vision
- weight loss
- tiredness
- recurrent skin infections
- Type II diabetes may not be diagnosed until features of diabetic complications are present
- increased screening of patients at high risk of diabetes may lead to earlier diagnosis before onset of complications

Diabetes may be picked up during a routine health check if:

- glucosuria or elevated BMs are found
- confirmation will require a diagnostic blood glucose measurement

All actions, clinical notes and test results are documented on an Electronic Patient

2 & 3	Protocol (investigations and management)
Staff:	Nurse, General Practitioner

P Annual:

- Foot check – peripheral pulses and sensation with 10g monofilament
- Retinal screening – a photograph is taken of the patient's retinae
- Test for protein (micro/macro) – early morning specimen taken – if no overt proteinuria the specimen is sent for microalbumin
- Height and weight – BMI
- Blood pressure measurement
- Check smoking status – give cessation advice if needed
- Blood tests – HbA1c, urea and electrolytes, eGFR, serum lipids, glucose level, thyroid function, full blood count
- Administer flu injection (or check if already had for that year) – check pneumococcal vaccination has been given
- Depression screening
- Review of medication – this includes diet and lifestyle measures which are reinforced at each visit irrespective of whether they are on medication for diabetes or not.

6 monthly:

- Blood tests as above (minus TFT)
- BMI and BP
- Review of medication
- Smoking status

All actions, clinical notes and test results are documented in an Electronic Patient Record

4	Decision on Therapy – Blood Glucose Control
Staff:	Nurse, General Practitioner

This is made at the review visit following blood tests where results are reviewed and a decision made as to whether patient stays at his or her current level of treatment. This may be non-pharmlogical – (diet and lifestyle) only.

If control is thought to be unsatisfactory then drugs can be increased or another agent introduced depending at what level the patient is already at and on how the patient's kidney function is.

The normal progression for medication once diet and lifestyle measures are no longer effective on their own can vary depending on patients' tolerability of medicines, renal function and their weight.

A typical Type II diabetic who is overweight and with normal or near normal renal function will be commenced on metformin which is weight neutral (sometimes it will help weight loss). This would be followed by a sulfonylurea (such as gliclazide). Sometimes a glitazone will be added – if renal and liver function permits. Newer agents are now available – DPP4 inhibitors and GLP1 analogues but these are not being widely used in primary care at the moment. Acarbose and postprandial stimulants such as nateglinide are also available but are not popular choices. Once all oral options are exhausted or if renal function is poor the only real option left is insulin. This is often threatening for patients as they fear injections more than most things. It takes time and patience to deal with patients once they get to this phase of their diabetes.

Blood Glucose Control (Source Map of Medicine)

Advise patient that maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimise risk of developing diabetic complications.

If there is evidence of increased arterial disease risk (raised albumin excretion rate, features of metabolic syndrome or other arterial risk factors), consider HbA1c of 6.5% or less

Advise patient that any reduction from initial levels is beneficial in the mid- and long-term, even if target level is not reached

For patients at high risk of hypoglycaemia consider the advantages and disadvantages for patients before pursuing tight blood glucose control, including:

- potential harms from hypoglycaemia
- any restrictions on quality of life needed to achieve target levels

Measurement of HbA1c

Every 2-6 months until the blood glucose levels is stable on unchanging therapy - ask about hypoglycaemia

6 monthly intervals once the blood glucose level and treatment are stable [2,6]

Frequency depends on:

- level of blood glucose control
- stability of blood glucose control
- change in insulin dose or regimen

All actions, clinical notes and test results are documented in an Electronic Patient Record

5	Decision on Therapy – Lifestyle
Staff:	Nurse, General Practitioner

As previously stated dietary management and lifestyle are reinforced at each visit irrespective of which therapy.

Individualised and ongoing nutritional advice from a healthcare professional with specific expertise and competencies in nutrition will be provided

All actions, clinical notes and test results are documented in an Electronic Patient Record

6	Insulin Therapy
Staff:	Nurse, General Practitioner

Previously covered in point 4 –Type I diabetics will always be on insulin – the dose and regime may change from time to time but otherwise there will be no other diabetic management – the other management will be around the complications – cardiovascular management, renal management, management of foot and neuropathy problems.

Unlike secondary care all medication is usually self-administered by the patient (or the parent or carer). Nurses and doctors rarely become involved in medicine administration. A structured programme is used that includes:

- blood glucose control
- structure education
- continuing telephone support
- frequent self-monitoring
- dose titration to target
- dietary understanding
- management of hypoglycaemia
- management of acute changes in plasma glucose control
- prevention and early detection of complication

All actions, clinical notes and test results are documented in an Electronic Patient Record

7	Complications
Staff:	Nurse, General Practitioner, Specialist

If complications are detected the patient will be referred to a specialist service which takes place outside of General Practice – this is like a hub away from the GP circle.

Complications Detected

- Cardiovascular Team
- Renal Team
- Ophthalmology
- Vascular Surgeon
- Neurologist
- Obs Gynae – pregnant patients only

Other patients – paediatric and complex type one patients will normally be reviewed annually in Diabetic secondary care clinics.

However these patients will be seen regularly in primary care for many reasons and for this reason the General Practice Team will always be a place that the diabetic patient can come for any help or assistance with managing their condition.

All actions, clinical notes and test results are documented in an Electronic Patient Record

8	Re-review
Staff:	Nurse, General Practitioner

Every six months the patient will be invited for further review – if there are complications then they may be seen more frequently – this is done on an individual basis and is based solely on the needs of the patient.

All actions, clinical notes and test results are documented in an Electronic Patient Record

9	End of Process
Staff:	Nurse, General Practitioner
There is no end of process in primary care – the patient will only leave our care if they die or leave the practice due to moving away from the practice catchment area. This is part of the general practice relationship that we have ongoing with our patients and what makes it very different from secondary care.	

4.6   Description of Future Workflows with the REACTION Platform

The goal of outpatient case management using the REACTION platform is to facilitate better glycaemic control in patients with diabetes. Moreover, it is the goal is to better control the total health status of patients with co-morbidities, which is present in practically every diabetic patient. Managing the entire health status is a prerequisite for good diabetic management.

Further, it is the goal to provide a tool for patients to monitor and manage their chronic illness, including tools for improving lifestyle and facilitate lifestyle changes.

Finally, it is the goal to facilitate interdisciplinary workflow and case management across the entire spectrum of stakeholders including: Health professionals at the health clinic (General Practitioners, nurses, therapists, administrators); external healthcare professionals (at the hospital and specialised clinics, liaison groups, social workers, pharmacists); as well as the patient hem- or herself including the immediate environment of informal carers (family members, friends, neighbours).

Figure 10 shows the part of the future workflow for diabetes management relevant to the group of professional carers and the patient.
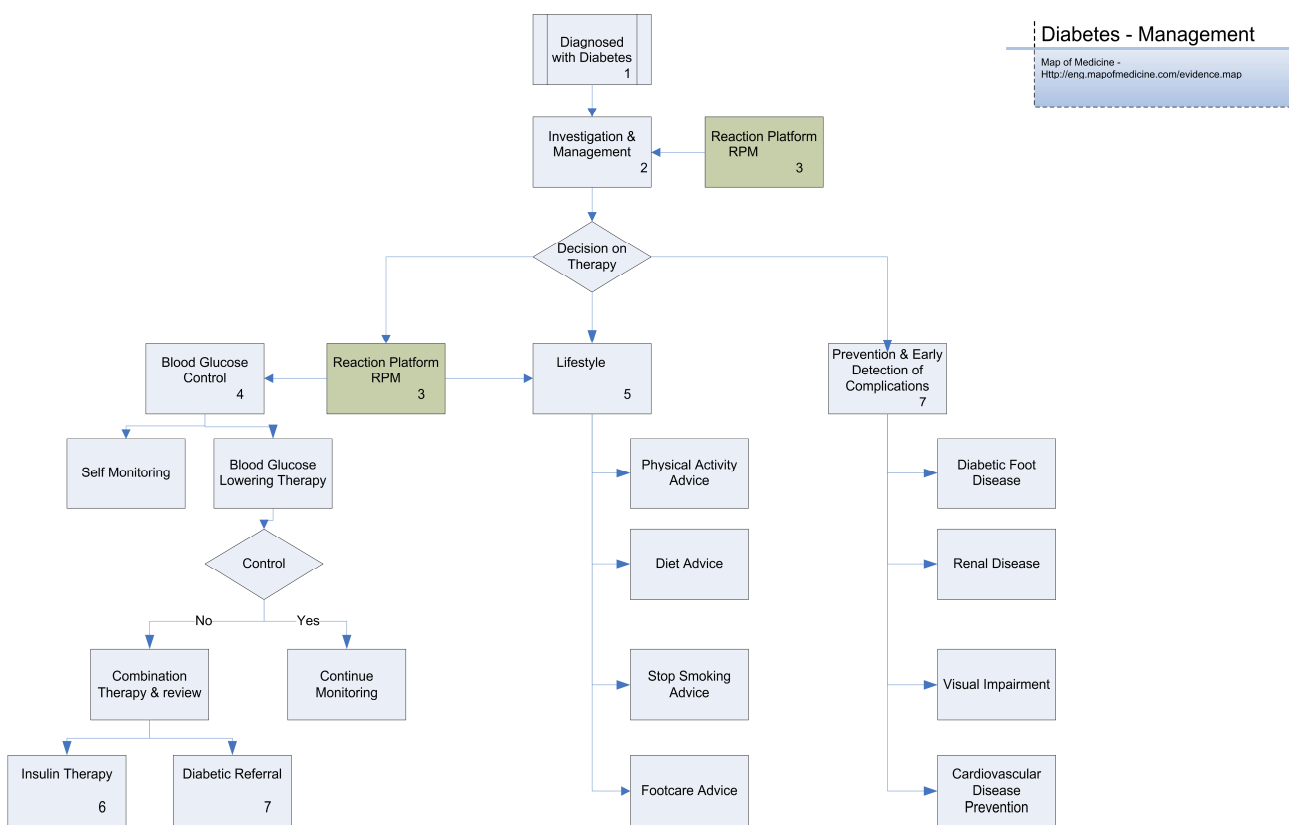

Figure 10 Future workflow for management of diabetes

4.7   Description of the Steps in the Future Workflow

1	Start of Process
Staff:	Physician, nurse

Patients are identified as having diabetes; some patients have presented with symptoms or have had screening which has confirmed that they have diabetes. Patients are entered on to an electronic register and are then invited to attend a Diabetic Clinic at the health centre for a review every six months

Clinical Presentation (Source Map of Medicine). Diabetes can present as a hyperglycaemic emergency, symptomatically or be discovered during a routine health check:

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- Type II diabetes may not be diagnosed until features of diabetic complications are present
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Diabetes may be picked up during a routine health check if:

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- confirmation will require a diagnostic blood glucose measurement

All actions, clinical notes and test results are documented in an Electronic Patient Record.

2	Protocol (investigations and management)
Staff:	Nurse, General Practitioner

P Annual:

- Foot check – peripheral pulses and sensation with 10g monofilament
- Retinal screening – a photograph is taken of the patients' retinae
- Test for protein (micro/macro) – early morning specimen taken – if no overt proteinuria the specimen is sent for microalbumin
- Height and weight – BMI
- Blood pressure measurement
- Check smoking status – give cessation advice if needed
- Blood tests – HbA1c, urea and electrolytes, eGFR, serum lipids, glucose level, thyroid function, full blood count
- Administer flu injection (or check if already had for that year) – check pneumococcal vaccination has been given
- Depression screening
- Review of medication – this includes diet and lifestyle measures which are reinforced at each visit irrespective of whether they are on medication for diabetes or not.

6 monthly:

- Blood tests as above (minus TFT)
- BMI and BP
- Review of medication
- Smoking status

All actions, clinical notes and test results are documented in an Electronic Patient Record.

3	Protocol (investigations and management) – Reaction Platform - RPM
Staff:	Nurse, General Practitioner, Telehealth Support Team

The Reaction platform will be used to support various stages within Diabetes Management in Primary Care:

Newly Diagnosed - used in the investigative stage to:

- Confirm diagnosis
- Provide feedback to clinicians and patients on effectiveness of lifestyle and or medication therapies
- Safely optimise dosage
- Form part of the patient education on diabetes
- Reassure patients concerned about their blood sugars

Medication Titration:
- Provide feedback to clinicians and patients on effectiveness of lifestyle and or medication therapies
- Safely optimise dosage
- Reassure patients concerned about their blood sugars

Ongoing Management:
- Support patients who are having difficulty managing their diabetes
- Provide feedback to clinicians and patients on effectiveness of lifestyle and or medication therapies
- Provide reinforcement to patients of required lifestyle changes
- Form part of the patient education on diabetes
- Used as part of a screening programme to identify better diabetes management for patients

Patients will be provided with a monitoring device. Clinicians and / or the Telehealth Support Team will view this data each day to review each patints progress against individualised targets for the patients.

All actions, clinical notes and test results are documented in an Electronic Patient Record.

4	Decision on Therapy – Blood Glucose Control
Staff:	Nurse, General Practitioner

This is made at the review visit following blood tests where results are reviewed and a decision made as to whether patient stays at his or her current level of treatment. This may be non-pharmological – (diet and lifestyle) only.

If control is thought to be unsatisfactory then drugs can be increased or another agent introduced depending at what level the patient is already at and on how the patient's kidney function is.

The normal progression for medication once diet and lifestyle measures are no longer effective on their own can vary depending on patients' tolerability of medicines, renal function and their weight.

A typical Type II diabetic who is overweight and with normal or near normal renal function will be commenced on metformin which is weight neutral (sometimes it will help weight loss). This would be followed by a sulfonylurea (such as gliclazide). Sometimes a glitazone will be added – if renal and liver functions permit. Newer agents are now available – DPP4 inhibitors and GLP1 analogues but these are not being widely used in primary care at the moment. Acarbose and postprandial stimulants such as nateglinide are also available but are not popular choices. Once all oral options are exhausted or if renal function is poor the only real option left is insulin. This is often threatening for patients as they fear injections more than most things. It takes time and patience to deal with patients once they get to this phase of their diabetes.

Blood Glucose Control (Source Map of Medicine):

Advise patient that maintaining glycated haemoglobin (HbA1c) below 7.5% is likely to minimise risk of developing diabetic complications

If there is evidence of increased arterial disease risk (raised albumin excretion rate, features of metabolic syndrome or other arterial risk factors), consider HbA1c of 6.5% or less

4	Decision on Therapy – Blood Glucose Control

Advise patient that any reduction from initial levels is beneficial in the mid- and long-term, even if target level is not reached

For patients at high risk of hypoglycaemia consider the advantages and disadvantages for patients before pursuing tight blood glucose control, including:

- potential harms from hypoglycaemia
- any restrictions on quality of life needed to achieve target levels

Measurement of HbA1c:

Every 2-6 months until the blood glucose levels is stable on unchanging therapy - ask about hypoglycaemia

6 monthly intervals once the blood glucose level and treatment are stable [2,6]

Frequency depends on:

- level of blood glucose control
- stability of blood glucose control
- change in insulin dose or regimen

All actions, clinical notes and test results are documented in an Electronic Patient Record.

5	Decision on Therapy – Lifestyle
Staff:	Nurse, General Practitioner

As previously stated dietary management and lifestyle are reinforced at each visit irrespective of which therapy.

Individualised and ongoing nutritional advice from a healthcare professional with specific expertise and competencies in nutrition will be provided

All actions, clinical notes and test results are documented in an Electronic Patient Record.

6	Insulin Therapy
Staff:	Nurse, General Practitioner

Previously covered in point 4 –Type I diabetics will always be on insulin – the dose and regime may change from time to time but otherwise there will be no other diabetic management – the other management will be around the complications – cardiovascular management, renal management, management of foot and neuropathy problems. Unlike secondary care all medication is usually self-administered by the patient (or the parent or carer). Nurses and doctors rarely become involved in medicine administration. A structured programme is used that includes:

- blood glucose control
- structured education
- continuing telephone support
- frequent self-monitoring
- dose titration to target
- dietary understanding
- management of hypoglycaemia
- management of acute changes in plasma glucose control
- prevention and early detection of complication

All actions, clinical notes and test results are documented in an Electronic Patient Record.

7	Complications
Staff:	Nurse, General Practitioner, Specialist

If complications are detected the patient will be referred to a specialist service which takes place outside of General Practice – this is like a hub away from the GP circle.

Complications Detected

- Cardiovascular Team
- Renal Team
- Ophthalmology
- Vascular Surgeon
- Neurologist
- Obs Gynae – pregnant patients only

Other patients – paediatric and complex type one patients will normally be reviewed annually in Diabetic secondary care clinics.

However these patients will be seen regularly in primary care for many reasons and for this reason the General Practice Team will always be a place that the diabetic patient can come for any help or assistance with managing their condition.

All actions, clinical notes and test results are documented in an Electronic Patient Record.

8	Re-review
Staff:	Nurse, General Practitioner

Every six months the patient will be invited for further review – if there are complications then they may be seen more frequently – this is done on an individual basis and is based solely on the needs of the patient.

All actions, clinical notes and test results are documented in an Electronic Patient Record.

9	End of Process
Staff:	Nurse, General Practitioner

There is no end of process in primary care – the patient will only leave our care if they die or leave the practice due to moving away from the practice catchment area. This is part of the general practice relationship that we have ongoing with our patients and what makes it very different from secondary care.

## 4.8   Future Clinical Pathway with Remote Patient Monitoring

The REACTION platform will be supporting adherence to clinical pathways, education, and self management health services for diabetes related conditions. Furthermore, clinical intervention for patients can be targeted to those with need; those that are well controlled will have less need for routine check up, and those above guidance levels will receive pro-active timely intervention.

Based on existing clinical pathways and workflows, a possible future clinical pathway supported by Remote Patient Monitoring and associated workflows have been developed.

The following clinical pathway illustrates how the healthcare professionals (users) would incorporate the REACTION platform for increased monitoring and integrate it into the daily workflows in the outpatient clinic. As can be seen, the pathway includes all professional stakeholders: the primary care team in general practice, the hospital care team as well as the community and social care teams.

While new monitoring schemes will allow better management of diabetes to reduce the burden of chronic diabetic complications, technological aids are needed to improve prevention of further complications of diabetes itself. Although pharmacologic prevention cannot be excluded in the next future, lifestyle modification will remain a necessary (and powerful) tool.

An important element of future pathways will thus be the inclusion of patients and informal carers in the process. Care spaces needs to be developed where the roles and tasks are distributed among the multidisciplinary health care team members, and providing the patient with his own self management tasks in an ongoing relationship with the other members of the team.
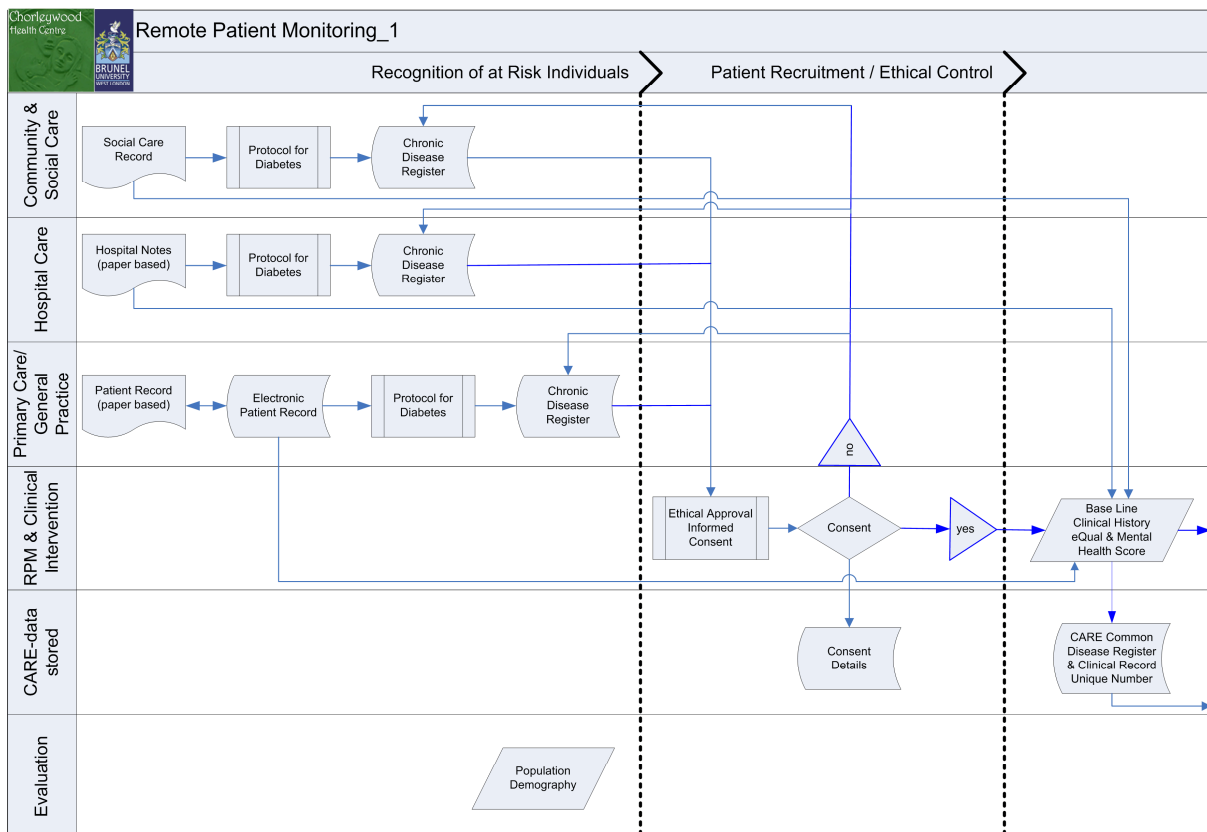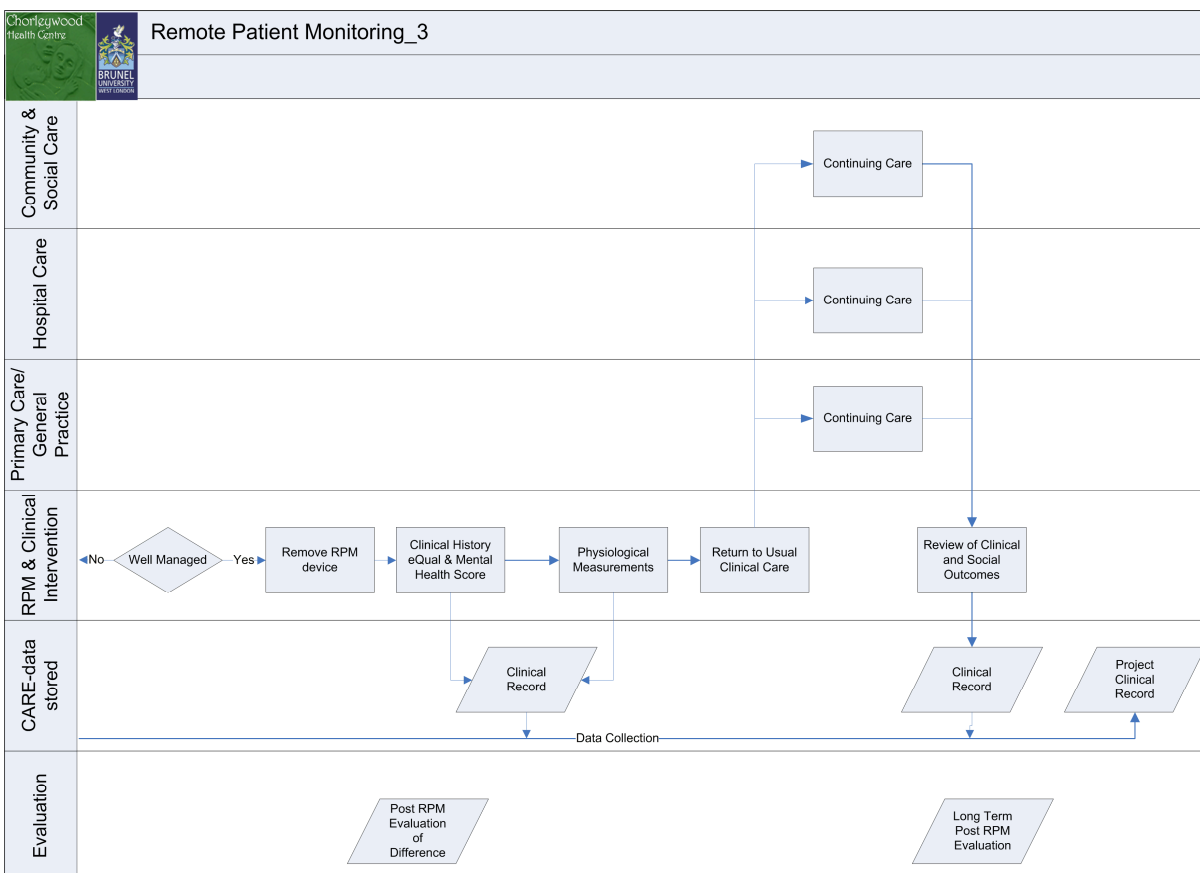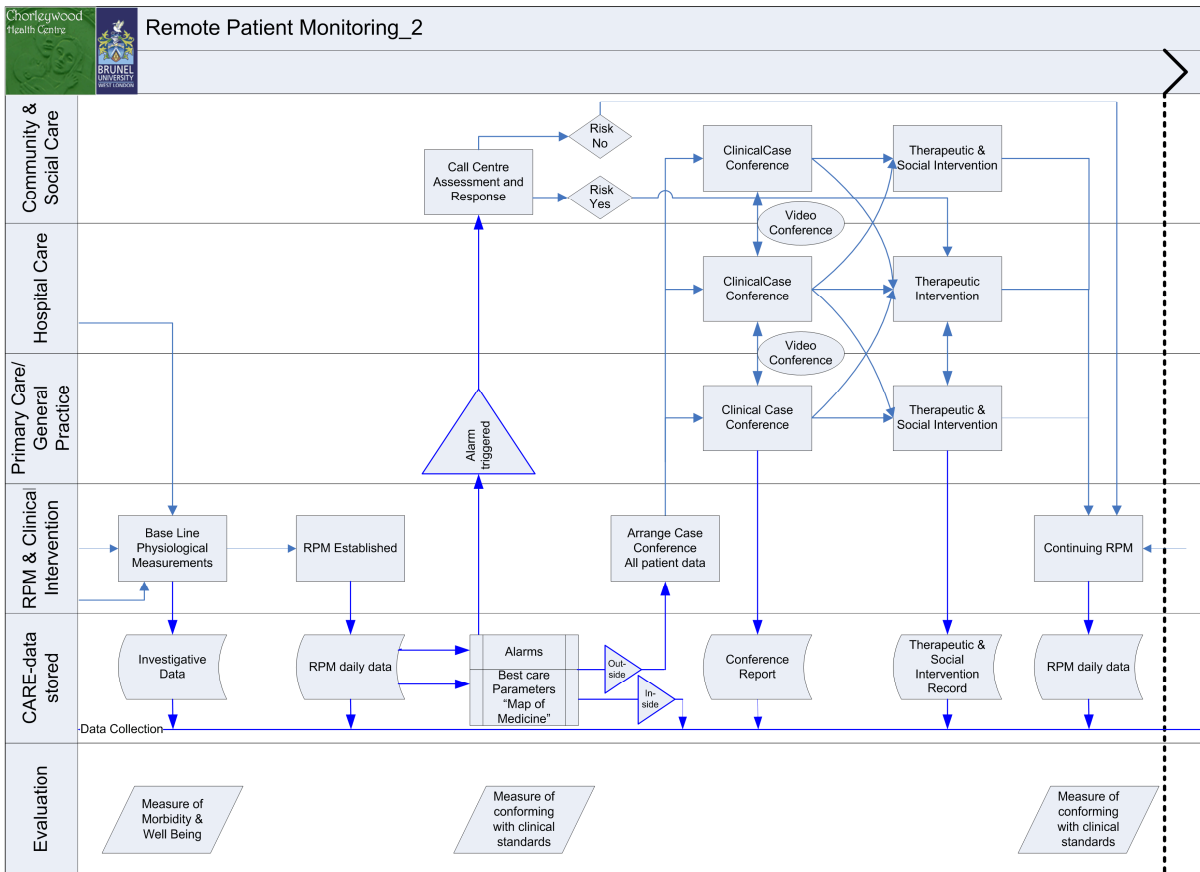

to be continued on the following page…

Figure 11 Future pathway for management of diabetes with the REACTION platform

4.9   Future Workflows using the REACTION platform

The clinical pathway includes a number of elements that are not related to physical actions, which is supported by the RECTION platform (such as clinical conferences). We have thus extracted the essential workflows for a personalised care plan and associated workflows incorporating Remote Patient Monitoring.

The development of a care plan requires up-to-date knowledge of the physicians and other professionals of the team and also the collaboration of the patients and their informal carers. Moreover, since the care is dynamic its plan should also be regularly reconsidered. Each care plan requires efficient and complete implementation, which presupposes appropriate organisation of the participants of the care process. This is given by an adequate care model.

The personalised plan should be implemented by the physicians and other professionals (e.g., nurses, nutritionists, and coaches) and patients themselves working together to ensure that patients reach their clinical goals. This implementation requires collaborative work with cooperative problem solving and decision making. Moreover the cooperation presupposes a certain level of concordance between the patient and the medical professionals. The latter requires a certain level of skill from the patient.

4.9.1   Setting up a Personalised RPM Care Plan

Figure 12 shows the initial steps (configuration) that need to be carried out when a new patient is enrolled in monitoring scheme using the REACTION platform. The conditions for monitoring are subject to specific approval (informed consent) by the patient and are directly influencing the setup of the monitoring scheme (privacy, access rights, frequency of monitoring, black-out times and places, etc). Also the case history and the baseline physiological measurements dictate important clinical aspects of the monitoring scheme.
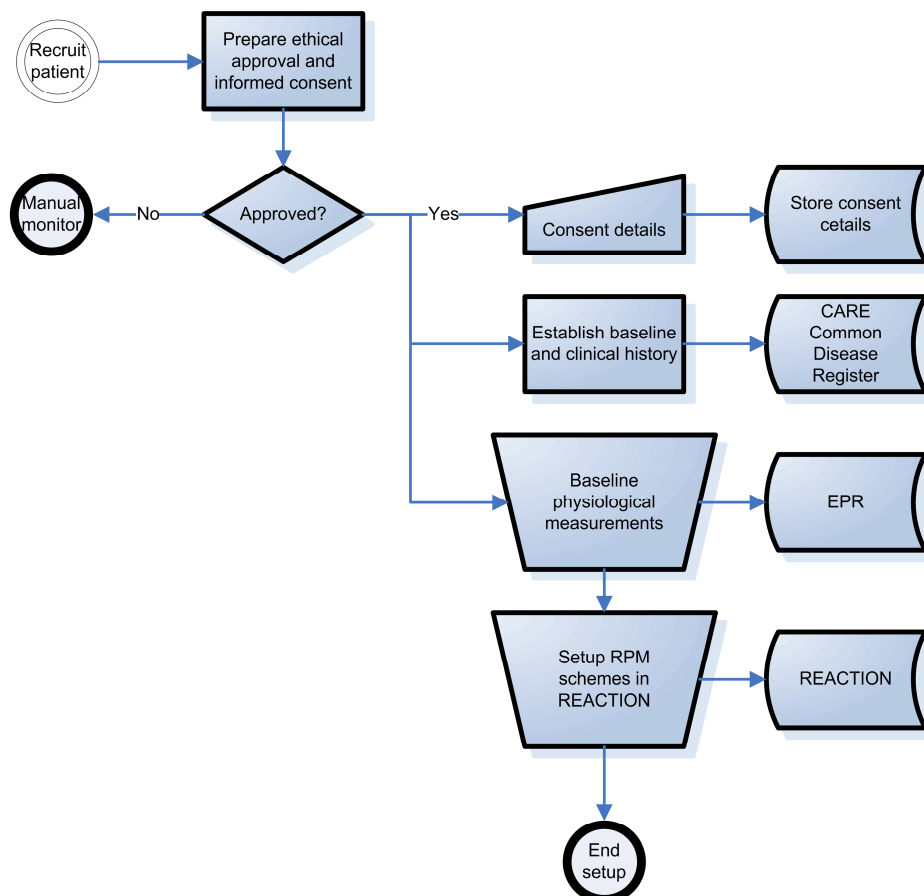

Figure 12 Initial workflow for enrolling patients in RPM

4.9.2   Executing a Personalised Care Plan with Remote Monitoring

Once the patient is enrolled in the personalised care plan, the REACTION platform is set up to support the workflows and to take over the personalisation and contextualisation of the care model.

Generally, the care plan: (i) should be personalized; (ii) should have disease management component, which permits to plan the treatment process focusing on the quality of life and health status optimisation; (iii) should have risk management component, which permits to select the parameters to monitor and plan the corresponding monitoring; and (iv) should have lifestyle planning component that permits to plan patient education and tailor the patient's lifestyle.

Figure 13 shows a simple workflow for collecting physiological parameters, comparing them with established standards and clinical practice with subsequent intervention by health and social care professionals in case of deviations.
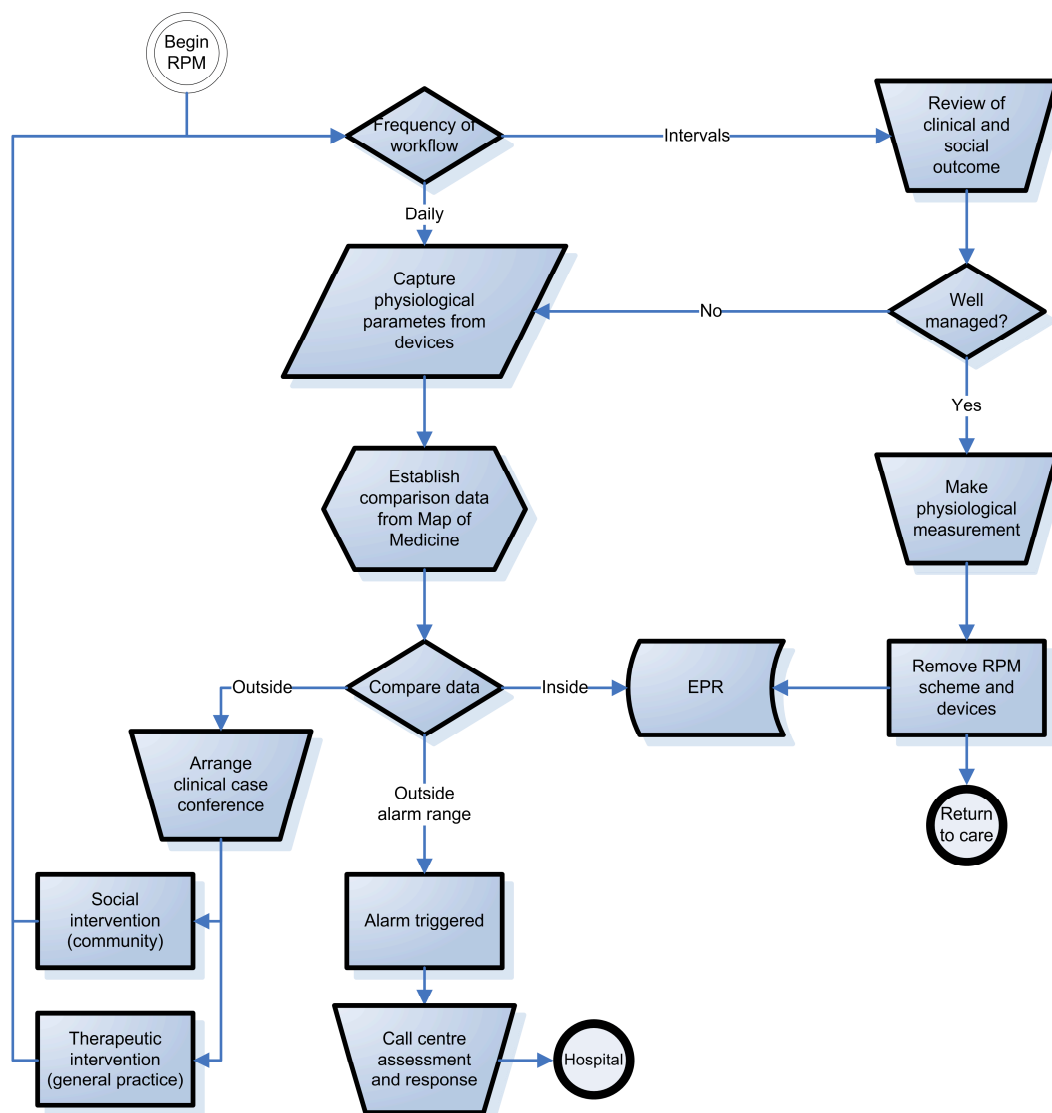
Figure 13 Simple workflow for Glucose Monitoring

Monitoring of multiple parameters may represent a useful integrated basis for achievement of strict and sustained glucose control that will provide a better opportunity to reduce diabetic complications and improve patients' quality of life. The use of movement sensors, calorie balance and media tools supported by the REACTION platform will serve to implement applications to monitor lifestyle modifications. These procedures can become cost effective if implemented in high risk individuals.

5.   Existing and Future Workflows in In-hospital Care

5.1   Description of the Domain

In-hospital hyperglycaemia has been found to be an important marker of poor clinical outcome and mortality among diabetic patients (Umpierrez2002). The in-hospital care application domain of the REACTION platform will feature a suite of services aiming at Tight Glycaemic Control (TGC) of diabetic patients in the general hospital ward using continuous glycaemic monitoring and closed-loop feedback to the healthcare professionals at the point of care.

Although several guidelines for treatment regimen for outpatient management of Type II diabetes have been defined (Sakharova2005); (Charles2005); (Inzucchi2006), no clear definitions of treatment regimen have been found for the establishment of glycaemic control of hospitalised patients (Clement2004, ADA2010).

5.2   Medical Significance

Hyperglycaemia and insulin resistance are common in severe illness and are often associated with physical and mental stress. Stress-induced hyperglycaemia can lead to significant deterioration in glycaemic control in individuals with diabetes and can cause stress-induced diabetes mellitus in non-diabetic patients. Studies have shown that frequency of hypoglycaemia in surgical ICU's (Intensive Care Units) can amount to 15 - 17 % of all admitted patients (Ellmerer2008) and there are increasing efforts world-wide to establish tight glycaemic control in critically ill and hospitalised patients.

Hyperglycaemia and use of aggressive insulin therapy in surgical ICU's is relatively well known. Not so for the much more widespread cases of stress-induced hyperglycaemia in the 90 % of patients not admitted to an ICU but to a general ward. Especially for the approximate 40 % of patients with diabetes (diagnosed or unrecognized), stress induced hyperglycaemia can have very adverse consequences.

Today's commercial CGM may well show errors up to 20%, in some situations even more, but they can still provide useful support for insulin therapy. The additional use of optimised algorithms for glucose control can help alleviate the problem, since trends in blood glucose level are continuously monitored and preventive action taken earlier. Even without high absolute accuracy continuous glucose measurement with discontinuous calibration combined with biomedical modelling may offer a revolution in disease management where the focus is on stabilisation of glucose levels, i.e. primarily the prevention of excursions of any type, instead of comparing current glucose levels with lower and upper thresholds.

Aggressive treatment of stress-induced hyperglycaemia has shown remarkable results in recent years. In a randomized, controlled study conducted in a surgical intensive care unit (Vandenberghe2001), strict control of blood glucose levels with insulin reduced morbidity and mortality, significantly reducing in-hospital mortality from 11 to 7 percent in the entire study population. Strict glycaemic control also decreased morbidity from bloodstream infections by 46%, acute renal failure requiring dialysis or hemofiltration and critical illness polyneuropathy.

The consensus panel of the American Diabetes Association reviewed research together with the original investigators to formulate standards for diabetes management in the hospital. The panel concluded that hospitalised patients should have a target glycaemic fasting level of <140 mg/dL (7.8 mM) and that insulin, whether administered intravenously or subcutaneously is the primary means of effective glycaemic control in the hospital setting (ADA 2010).

During the last years in the literature (in particular for glycaemic control in the ICU) "Tight Glycaemic Control" (TGC) was used. The target range was between 80-110 mg/dl. With the NICE sugar trial (NICE2009) it was shown that TGC (80-110 mg/dl) is not beneficial for the patients suggesting a higher target (one of the reasons was the higher number of hypoglycaemic events in the intensified group which was associated with a worse outcome). This was the start of a debate about the target range - a debate which is still going on. All agree that hyperglycaemia is not good for the patients but everyone has a different definition of hyperglycaemia. We do not want to step in this discussion. We would like to reduce hyperglycaemia without generating hypos ("Safe Glycaemic Control") aiming at a target level which is higher than the fixed 80-110 mg/dl, perhaps adapted to each individual depending on the history and actual state of the patient.

5.3   Clinical Significance

One of the major differences between in-hospital and outpatient control of glycaemic levels is the fact that tight glycaemic control in hospitalised patients has to be provided by healthcare physicians and/or nurses. Achieving the goal of tight glycaemic targets requires extensive nursing efforts, including frequent bedside glucose monitoring, training to handle control algorithms or guidelines with intuitive decision taking and most importantly additional responsibility to prevent hypoglycaemic episodes.

The common general ward workflow for good glucose control requires that blood samples be taken, identified and transported to the central laboratory. After analysis, the results are transmitted to the physician or nurse for evaluation and validation. Often, dedicated insulin therapy specialists, with training in handling control algorithms or guidelines for therapy, need to be involved in the validation. Only then can the therapy be safely applied. This procedure causes delays of hours and even days, which is highly problematic considering that TGC ideally requires measurements to be made every 3-4 hours. The entire process is moreover subject to errors, a situation that is compounded by the changing of the treating physician.
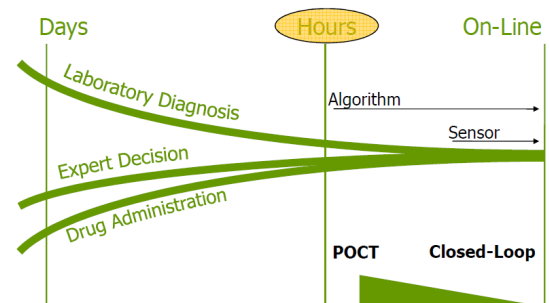

Figure 14 Evolution of BG control

In the general ward a REACTION application must monitor a range of parameters including blood glucose, nutritional intake as well as measures of insulin sensitivity. The data will be contextualised in the Data Management component and mathematical algorithms will be used to calculate the required insulin doses. Results will be fed to dedicated diabetes experts specialised in glycaemic control (usually located in a specialist diabetes centre) for verification and evaluation. Their appraisal will then, on-line, be fed back to the physicians and nurses at the point of care in the patients ward.

For the implementation of the new REACTION application, hospital systems will need to be adapted and hospital and ward-wide protocols for administration and monitoring of blood glucose levels and insulin infusions will be required. Besides that, and for risk mitigation purposes, protocols for risk management of hyperglycaemia need to be established.

Daily insulin treatment follows the natural workflows of humans based on three daily meals and a prolonged cycle of rest. This process is visualised in Figure 15.

The three meals are distributed over morning, mid day and evening. During and after meal intake the blood glucose level rises due to carbohydrates. In non-diabetic patients, this is compensated with the release of insulin from the pancreas resulting in a well controlled, steady glucose level. In diabetic patients, or patients with temporary insulin resistance, the flow of insulin is either reduced or non-existing and has to be compensated with manual injection of insulin.
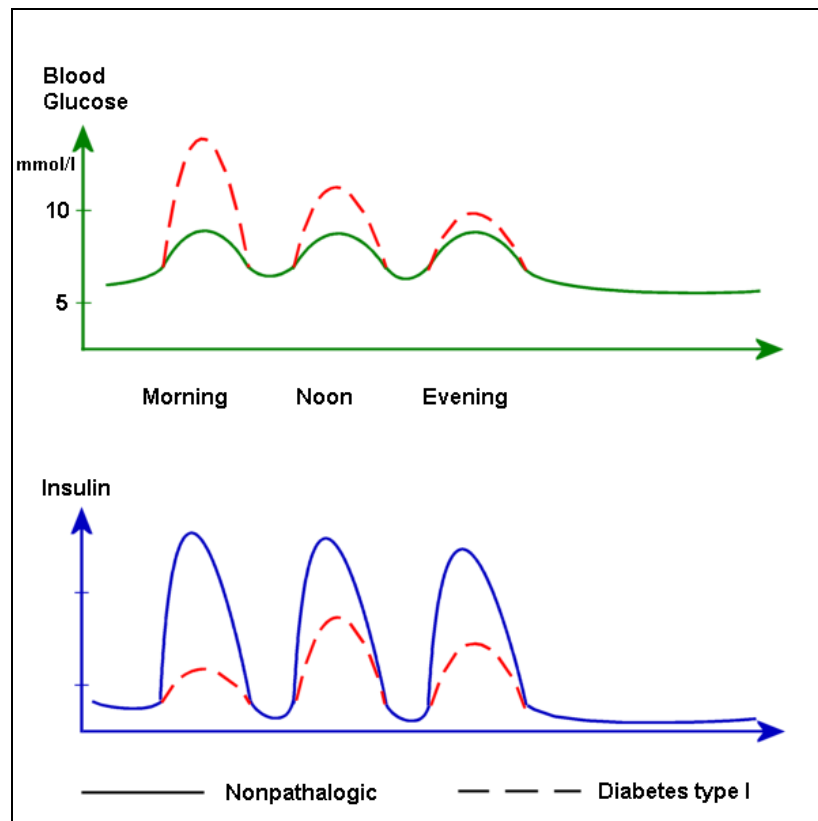
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Figure 15 Loops in the central workflows in insulin based treatment

For a normal individual, the pancreas delivers insulin closely adjusted so that there is always the right amount of insulin "on board" to keep the blood glucose levels in the appropriate range between 5 and 10 mmol/l (visualised with the solid curves). For a patient with diabetes type I, the amount of insulin has to be injected, which is not always precise. The resulting blood glucose is thus most often not in the normal range, but tends to be higher (hyperglycaemic) due to the risk of a hypoglycaemic event.

The central workflow in insulin based treatment thus contains four loops:

- The first loop starts in the morning (morning loop): Determination of the fasting glucose level, breakfast (including calculation of the ingested carbohydrates), and dosing of insulin.

- The second loop starts with lunch (lunch loop): Determination of the pre-meal glucose level, lunch (including calculation of the ingested carbohydrates), and dosing of insulin.

- The third loop starts with dinner: Pre-meal glucose level, dinner (including calculation of the ingested carbohydrates), dosing of insulin.

- The fourth loop starts with bedtime: Determination of the glucose level, dosing of insulin (correction with bolus plus baseline with long acting insulin).

A REACTION field trial will be situated in a hospital setting to monitor blood glucose level. The data will be contextualised and provided to medical specialists and healthcare professionals for verification and evaluation at the point of care. A field trial will demonstrate the feasibility for Safe Glycaemic Control (SGC) in which continuous glucose monitoring measurements are used to control the insulin delivery of the infusion pump while at the same time closely monitoring signs of potentially life threatening hypoglycaemia. This would provide optimum management and could provide diabetes patients with insulin profiles close to that of the normal patient, although problems remain to develop long term accurate continuous monitoring systems, delivery systems, control algorithms and ensuring safety of the system (Steil 2002, Hovorka 2010).

5.4   The Hosting Institution

The Medical University Graz (MUG) has provided access to the 20-bed in-hospital department for planning and work-flow analyses and will carry out a number of field trials later in the project.

Medical University Graz is a young university, comprising 16 Research Institutes and 23 Clinical Departments as well as a Centre for Medical Research. MUG is embedded in a 1600 bed University Hospital located in Graz, Austria with over 6000 employees. The division of Endocrinology and Nuclear Medicine at the Department of Internal Medicine offers extensive outpatient services and a 20-bed in-hospital general ward with special emphasis in the treatment of diabetes and associated metabolic disorders.

Research interests of the division of Endocrinology and Metabolism focus on areas, such as overall metabolic control, pathophysiology of late complications, cardiovascular endocrinology, vascular biology and on the investigation of new pharmaceutical approaches for the treatment of diabetes.

The workflow of the in-hospital glycaemic management is impeded in the daily routine of the patients, the nursing- and the medical staff. Figure 16 describes the in-hospital daily routine related to glycaemic management of the 3 interacting groups: the patients, the medical - and nursing staff. The routine of the later two groups is very structured and standardised whereas the patients' workflows differs from day to day depending on the patients' health status as well as the planned examinations and its delays. These circumstances have to be taken into account for safe glycaemic control.
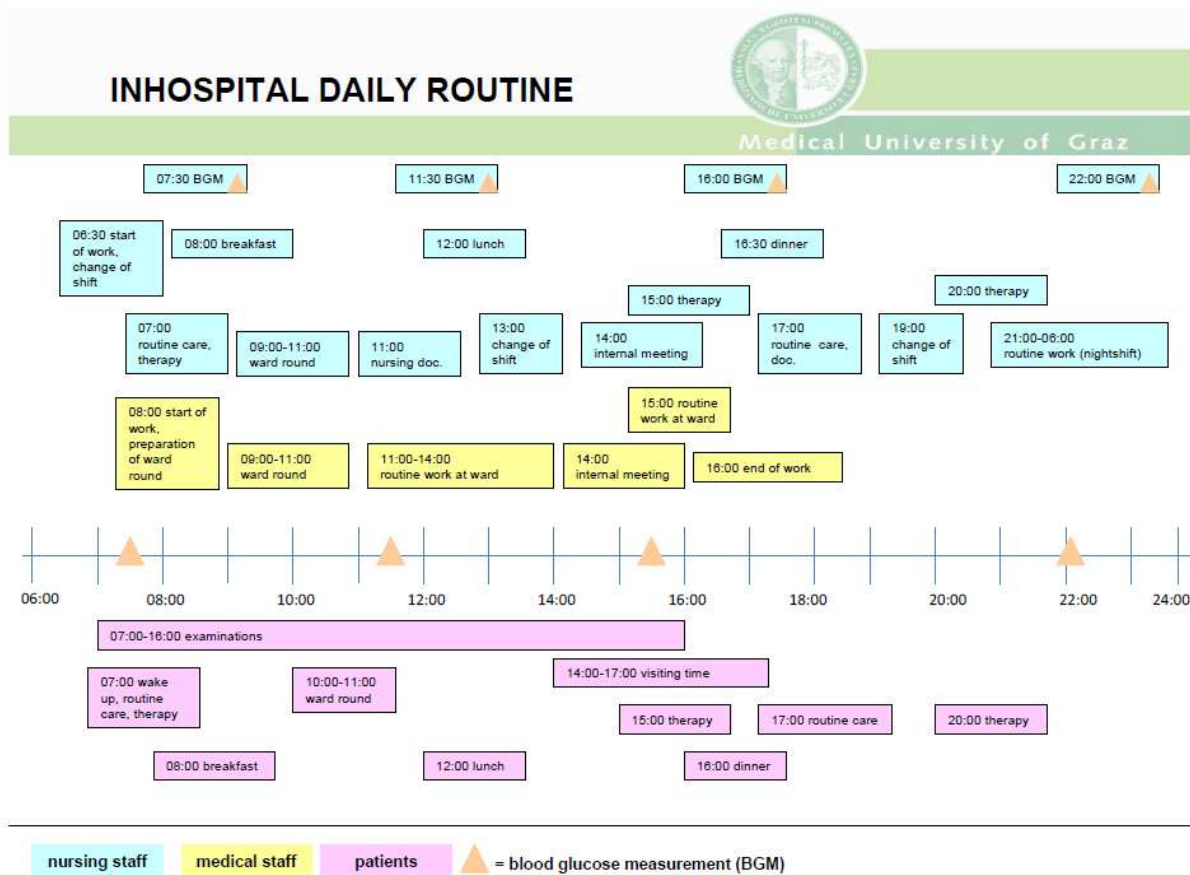
Figure 16 Daily in-hospital routine

Although the workflows of all three groups run independently, they have to fit with each other. This is in particular important in situations which occur outside of the daily routine. For example if the patient has an examination at 10:00, he would miss the ward round, which is at the same time every day. If the examination lasts two hours, the nurse cannot perform blood glucose management at the predefined time. The frequent occurrence of extraordinary events places tough requirements on the flexibility and re-configurability of the REACTION platform.

5.5   Description of Existing Workflows

This workflow describes the glycaemic management of a general ward in the hospital.

Figure 5: General workflow for the in-hospital glycaemic management

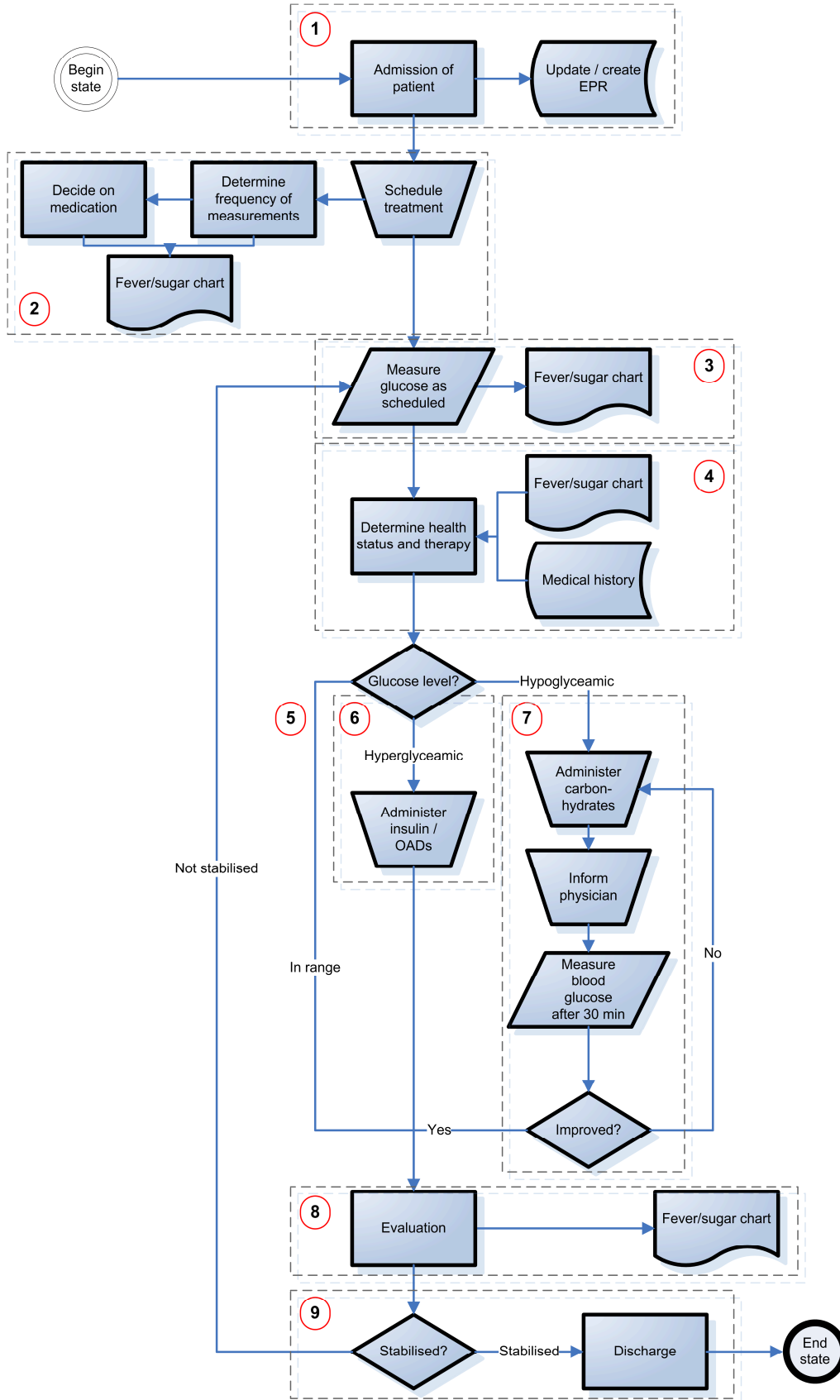## 5.6   Description of the Steps in the Existing Workflow

1	Start of the workflow

The workflow related to in-hospital glycaemic management starts with the admission of a patient with hyperglycaemia or with the diagnosis of diabetes mellitus. This is based on blood glucose measurements and/or medical history of the patient.

2	Schedule measurement/treatment
Staff:	Physician, nurse, patient

The physician has to define and document the treatment of the patient with hypergylcaemia or diabetes mellitus based on many important criteria:

- Medical history (medical diagnosis, diabetic status, HbA1c, target of glycaemia, medication),
- General health status (e.g. active-autonomous, frailty, nursing case),
- Actual status (treatment, infection, fever,.),
- Nutrition and associated conditions (fasting, special diet, diarrhea, vomiting, snacks in between, diminished/absence of appetite),
- Planned examinations/treatments (e.g. surgery, endoscopic interventions),
- Interaction with other medication (e.g. glucocorticoids).

The following tasks have to be documented:

- The physician defines at which time and how often the blood glucose should be measured (e.g. four times a day, fasting and premeal or just one fasting value in the morning).
- He also defines type (oral anti-diabetics or insulin (rapid-acting, basal insulin, pre-mixed)) dose and timing of medication.

The information is documented on a paperbased "fever/sugar chart".

3	Perform measurement
Staff:	Nurse, patient
Device:	POCT- Accu Chek Inform

Blood glucose measurements will be performed according to Standard Operating Procedure (SOP) with a POCT (Point of Care Testing) device: Roche Accu Chek Inform. Procedure of measurement:

- Disinfection of the finger, where the measurement will be done
- Pricking the finger using a lancet
- Transfer of blood on to the strip of the glucose meter
- Display of the glucose value
- Check plausibility
- Documentation of the measured value, time and comments (e.g. fasting, before/after meal) on the "fever/sugar chart".

Glucose measurements will be perfomed as initially defined (e.g. four times a day fasting and premeal or just one fasting value in the morning) after a certain period of time – depending on the chosen treatment.

In case of unexpected high or low glucose values frequence of glucose sampling may deviate for safety reasons.

4	Decision on therapy
Staff:	Nurse, patient

Based on patients history of diabetes and the current glucose measurements and associated parameters (the general health status, nutrition and conditions (fasting, special diet, diarrhea, vomiting, snacks in between, diminished/absence of appetite), planned examinations/treatments (e.g. surgery), interaction with other medication (e.g. glucocorticoide), the actual status (severity of illness, estimated insulin resistance, treatment, infection, fever,.)) the appropriate treatment will be selected to achieve a predefined target glucose range.

- Continue pre-existing therapy (oral anti-diabetics, insulin, diet)

- Adjust dosage of oral anti-diabetics

- Start additional oral anti-diabetic substance and/or add insulin to pre-existing oral anti-diabetic substance

- Stop oral anti-diabetics and start insulin

- Adjust insulin dose

- Change of insulin regime (e.g. basal insulin supplementation to premixed insulins twice daily or

- Pre-prandial rapid-acting insulin injection, change premixed insulin twice daily to intensified insulin therapy)

- Add oral anti-diabetic agents to pre-existing insulin therapy

- Stop insulin and start oral anti-diabetics

5	No specific treatment

In case the patient's glucose level is in the target range without any specific treatment or the patient has enough dose of insulin and or OADs "on board" no specific treatment will be performed.

6	Administer insulin/OADs
Staff:	Patient, nurse

In the case of hyperglycaemia or the likelihood that hyperglycaemia will occur (e.g. nutrition, administration of steroids, fever, …) insulin dosage and/or OADs will be adjusted accordingly

The insulin dose will be re-calculated. If the re-calculation differs significantly from the pre-calculated dose the nurse will consult the physician.

In the majority of cases the insulin injection will be given by the nurse subcutanously (e.g. insulin pen, syringe). Sometimes, in particular patients with Type I diabetes and active Type II diabetic patients with preexisting insulin therapy will perfom the insulin injection autonomously.

In rare cases of hyperglycemic emergencies or existence of severe insulin resistance insulin will be given intraveniously by an infusion pump.

The amount of insulin, time and carbohydrates will be manually transferred to the paper record.

Pill boxes, containing amongst others oral anti-diabetic agents, are distributed to the patients once a day.

7	Administer carbohydrates
Staff:	Nurse, patient, physician

The definition of symptomatic hypoglyceamia is a blood glucose value below 60 mg/dl (3.3 mmol/l) [=abitrary treshold] and the patient feels hypoglycaemic symptoms (sweating, headache, shivering,.). In case of a severe hypoglycemic episode the patient needs third party assistance.

In case of approaching hypoglycaemia, the patient gets carbohydrates orally (for example orange juice or dextrose). In case of severe hypoglycaemia glucose is given intravenously.

The hypoglycaemic event will be recorded (time, glucose value, treatment) on the "fever/sugar chart".

The nurse informs the physician about the hypoglycaemic event.

For safety reasons the blood glucose will be measured again after 30 min.

8	Evaluation
Staff:	Physician, nurse

In general, glyceamia and according treatment will be supervised by the medical and nursing staff within the ward round once a day. Adaption of therapy will be mainly performed based on the data recorded in the fever/sugar chart. In addition, the changes of anti-diabetic medication have to consider/focus on upcoming planned medical steps (e.g. reduction of glucose lowering medication if patient is fasting the next day).

However, at any point of glucose measurement, the dosing of medication should be evaluated by the nurse in charge. In case of a deviating glucose profile the schedule of blood glucose measurements and the regime has to be evaluated and new treatment adjusted after consulting the physician on-call duty.

All these actions will be ducumented manually in the paper record of the patient.

9	End of workflows

The workflows of the in-hospital glycaemic control management ends with the discharge of the patient.

5.7   Workflow Elements of the Glycaemic Management

Within the general workflow of glycaemic management several workflow elements can be identified. The workflow elements influence more or less the general workflow.

	Determination of the actual health status / diabetes mellitus
Relates to:	*1) Start of the workflow, 2) Schedule measurement/treatment*

At admission of the patient the actual health status will be determined by the physician.

Elevated glucose levels can be differentiated to the different kinds of diabetes (Type I, Type II, gestational, stress diabetes…). At admission of the patient the status of diabetes may be known or newly diagnosed. In the first case the actual treatment can be continued or adapted to the status of the patient. In the second case a dose-finding procedure for the individual patient will be started associated with education in nutrition and therapy.

	Decision on treatment
Relates to:	*2) Schedule measurement/treatment*

Starting point:
- Patient with known diabetes: therapy scheme may be continued
- Patient with newly diagnosed diabetes: therapy scheme has to be started
- Patient with stress diabetes: therapy scheme has to be started

Used drugs:
- Oral anti-diabetic drugs (OADs)
- Short / long acting insulin
- Mixed insulin

Therapy:
- OADs only
- OADs and insulin
- Intensified insulin therapy (separate substitution of basal and meal-related insulin)
- Conventional insulin therapy (premixed insulin twice daily)
- Continuous subcutaneous insulin infusion (CSII) – insulin pump
- Prandial insulin therapy (meal related injection of rapid acting insulin)

Issues which have to be considered:
- Actual therapy scheme
- Actual health status and associated conditions (fasting, special diet, diarrhoea, vomiting; infection, fever)
- Nutrition (snacks in between, diminished/absence of appetite)
- Insulin sensitivity (diurnal changes, fever…)
- Planned examinations/treatments (e.g. surgery, endoscopic examinations)
- Interaction with other medication (e.g. glucocorticoids)

Documentation:
- Which OADs (which time, dosage)
- Which Insulin (which time, how many units)
- Correction bolus (blood glucose, number of units insulin)
- Set glycaemic target range

Implementation:
- By nurses; in case of unexpected event by physician

	Perform measurement
Relates to:	*3) Perform measurement*

Instruction for measurement:
- WHO: physician
- WHEN: Fasting glucose or diurnal profile of glucose (3 times per day (plus one measurement before bedtime and on rare occasions 4-5 hours after basal insulin injection during night-time))

Device:
- POCT-Device: Login, patient identification, comment (e.g. fasting, pre-meal, …)

Procedure:
- Disinfection of the skin (finger)
- Pricking the finger with a lancet
- Transfer of capillary blood to the device
- Documentation of the blood glucose value
- Check plausibility

Documentation:
- Nurse: which time was the measurement performed (pre-prandial/ fasting)

Implementation:
- WHO: nurse
- WHEN: Pre-meal at the times defined by the physician

	Determination of glucose by phlebotomists
Relates to:	*3) Perform measurement*

In the hospital with associated laboratories there exists the possibility that specially trained nurses (phlebotomists) visit the patients in order to collect blood samples. The nurses are requested by the physician and get a list of the relevant parameters to be determined. After collecting the blood samples they are transferred to the laboratory where they are measured. The results of the measurements will be available electronically in the hospital information system. There is a delay between collection of samples and results (up to several hours) thus this kind of glucose determination can hardly be used for online insulin adjustment.

	Inject insulin
Relates to:	*6) Administer insulin/OADs*

Starting point:
- Fever chart (OADs) and/or sugar chart insulin diary and actual blood glucose measurement)
- Therapy based on scheme fixed by physician
- Health status of the patient (fever, fasting …)

Decision on treatment:
- Therapy based on scheme fixed by physician
- In case glucose profile is deviating from glucose target range adaptation of treatment after consulting with on-call duty physician.

Procedure:
- Choice of body site where insulin will be injected (has to be documented)
- Local disinfection of the site of injection
- Inject insulin using an insulin pen or a syringe filled with the appropriate insulin
- Documentation amount of insulin and time of injection

	Discussion of Blood Glucose values
Relates to:	*8) Evaluation*

When:
• Daily at the ward round

Objectives:
• Optimisation of therapy by adjustments
• Information exchange
• Quality control/improvement
• Teaching workflows

Education:
• Teaching of the patients by outpatient diabetic clinic
• Continuous teaching of the staff

Implementation:
• Physician
• Nurses
• Sugar Nurse
• Diabetes ward

Quality check:
• Once daily, in case of complications more often

	Examinations/treatments (e.g. surgery)
Relates to:	*2) Schedule measurement/treatment, 4) Decision on therapy, 8) Evaluation*

For some examinations/treatments in the hospital the patients have to be in a fasting and/or euglycaemic condition. Therefore the treatment is adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). A problem for the patient may arise if the patient has to wait longer than expected due to unexpected delays. This may result in glycaemic excursions (hyper- or hypoglycaemia).

Actions:
• Dose of insulin and/or OADs will be adapted
• The patient will get some food which he can eat in case of hypoglycaemia
• The patient will get insulin which will be injected in case of hyperglycaemia

	IV Insulin
Relates to:	*2) Schedule measurement/treatment, 3) Perform measurement, 4) Decision on therapy, 6) Administer insulin/OAD*

In some cases the patient will get insulin intravenously (e.g. fast or controlled glucose is required). Due to the fact that IV insulin reacts much faster than subcutaneous insulin this fact has to be taken into account in relation to nutrition and infusion of fluids containing glucose). In case the amount of nutrition is decreased insulin infusion has also to be decreased in order to prevent a hypoglycaemic event.

In the beginning blood glucose will be checked every 2 hours and will be recorded together with the insulin infusion rates in a separate sheet ("intensive graph") by the nurses.

	Hypoglycaemia
Relates to:	*4) Decision on therapy, 7) Administer carbohydrates*

Starting point:
- Glucose value below 60 mg/dl (3.3 mmol/l)
- Symptoms of hypoglycaemia (sweating, headache, shivering, loss of consciousness, convulsions…)

Reasons for hypoglycaemia:
- Inadequate treatment (e.g. overdosing of insulin)
- Change in nutrition (fasting without adjustment of insulin dose)
- Vomiting
- Changes of insulin sensitivity/resistance

Treatment:
- In case when patients feels hypoglycaemic symptoms blood glucose measurement will be taken
- Oral administration of carbohydrates
- IV administration of glucose (in severe hypoglycaemia)
- Documentation by the nurses (report, glucose graph) inc. glucose value, date, time, symptoms and administered carbohydrates
- Physician will be informed (documentation by physician)
- Check blood glucose after one hour (earlier in case of severe hypoglycaemia or if clinically indicated)

Documentation:
- Patient record („fever chart" of „sugar chart") by nurses
- Physician will be informed

	Hyperglycaemia
Relates to:	*2) Schedule measurement/treatment; 4) Decision on therapy; 6) Administer insulin/OADs, 8) Evaluation*

Starting point:
- Glucose values above a certain threshold (out of target range)

Reasons for hyperglycaemia:
- New onset of diabetes
- Inadequate treatment
- Administration of interfering drugs (e.g. glucocorticoids)
- Stress diabetes (severe illness, surgery…)
- Mental stress

Treatment:
- OADs
- Insulin
- OADs and insulin
- Hyperglycaemic coma: severe state of the patient, will be treated immediately by the physician

Documentation:
- Patient record („fever chart" of „sugar chart") by nurses

	Nutrition
Relates to:	*2) Schedule measurement/treatment, 4) Decision on therapy*

Starting point:
Nutrition has to be taken into account when calculating the dose of the drug. This is more crucial when the patient is treated with insulin (TD1, TD2 with insulin) than with OADs only. In special cases (extreme adipositas, lack of appetite, complications,…) a nutrition consultation by a dietician is requested. For Typ2 diabetes: the composition of food equals approx. 14 units BE (carbohydrate exchange) per day.

Issues to be considered:
- composition of the meals (proteins, fat, carbohydrates)
- snacks in between
- fasting
- special diet
- diarrhoea
- vomiting
- diminished/absence of appetite

Documentation:
- Nutrition and its associated problems

Implementation
- Nurses

	Special conditions related to nutrition (PEG tube / parenteral feeding)
Relates to:	*2) Schedule measurement/treatment, 3) Perform measurement, 4) Decision on therapy*

In the case the patient is not able to eat any more nutrition may be delivered by parenteral feeding or via PEG tube.

Due to the fast adsorbing status of the IV administered fluids the number of blood glucose measurements has to be adjusted.

	Interaction with other medication
Relates to:	*2) Schedule measurement/treatment, 4) Decision on therapy*

Some drugs interfere with glycaemic management:

- Systemic interference (e.g. cortisone by increasing blood glucose)

- Analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference)

These facts will be considered by the physician when defining the treatment.

	Fever/Infection
Relates to:	*2) Schedule measurement/treatment, 4) Decision on therapy*

Fever is very often associated with insulin resistance which means that the patient needs more insulin. Regular checks for prevalence of kenotic acid in the urine are performed to increase the insulin dose to the current needs.

Documentation:
- Patient record („fever chart" of „sugar chart") by nurse

	Documentation
Relates to:	*Entire workflow 1) to 9)*

Documentation is a central action in treatment and care workflows. There are several different documents and platforms for documentation:

- Hospital information system (MEDOCS) – electronically based system,

- patient record (paper based),

- "fever chart" (this chart contains not only the information about temperature but also vital parameters- heart rate and blood pressure, information about the actual status of the patient (vomiting, pain, faeces,.), relevant blood parameters and its changes, prescription of drugs and treatments (in some cases glucose measurements and insulin/OADs prescription). Therefore this document is considered as a central document; it is a paper based document

- "sugar chart": in many cases the information about glucose and its treatment is part of the "fever chart", in some wards the "sugar chart" is a document on its own (paper based)

- Documentation of the nurses is part of the hospital information system (MEDOCS)

- Laboratory information system (LIS) – this is an electronically based system which is linked to the hospital information system (MEDOCS)

5.8   Comparison of the Existing Workflow with the Future Workflow

The goal of in-hospital glucose management is to facilitate safe glycaemic control (SGC) in patients with hyperglycaemia (established or newly diagnosed diabetes, stress hyperglycaemia) in the General Ward (GW). There will be a stepwise approach for the implementation of SGC in the GW:

In the first step the current workflows related to glycaemic management at two different wards (Endocrinology and Cardiology) have been investigated. Out of these workflows user requirements were derived which should be the basis for the system specifications.

Existing workflow	Relation to workflows	Problems	Solutions
Documentation	1-9	Paper-based- access to the data only for one person at the same time	Electronic paperless data record (mobile access point, e.g. tablet PC)- access for more persons at the same time at different locations
Documentation	1-9	Difficult traceability of documentation and decision making	Usage of centrally managed data repositories- easy updating of information and access to latest version
Documentation	1-9	No data backup in case documents are lost	Information available even in case of a system breakdown- regular backup of data
Documentation	1-9	Fixed presentation of data	Different modes of visualisation with different relevant parameters for decision support
Decision making	2, 4	Suboptimal decisions and treatments- no standardised instructions and decisions	Electronic decision support system- standardised instructions and decisions (e.g. evidence based medicine, support identification of "patients at risk")
Perform measurements	3	Sometimes neglect to perform measurements	Active alarm system- reminder to perform measurements
Transfer of data into the record	1-9	Manually-labour intensive, risk of transcription errors, handwriting prone to errors	Automated transfer of measured and relevant data to the patient's record and hospital information system to avoid error prone and labour intensive procedure
Patient identification	1-9	Risk of wrong patient identification	Automated patient identification to avoid identification mistakes
Archive system	2, 4, 9	Challenge to retrieve archived data	Electronic archive system- easy available data from former admissions

Table 2 Description of workflows including current problems and solutions for the REACTION system

When analysing these workflows the following issues have to be taken into account:

- Electronic data record/chart (paperless chart). Problem: Currently all actions are recorded on a paper chart/record. Because of data privacy protection and safety issues this record must not stay at the patient's bed but will be stored centrally. The staff (nurse/physician) has to look for the patient record every time before he/she goes to the patient. This means that the information is only available for one person at the same time (i.e. if the nurse is at the patient with the record the physician- who may be in a different room- has no access to the data in order to discuss it with colleagues).

- Display and input of data should be possible at different locations simultaneously (mobile access points – e.g. tablet PC at point of care versus fixed access points – e.g. screens at physicians/nurses base)

    – A centrally managed data repository enables easy updating of information and access to the latest version of information from different access points simultaneously

- Information must be available also in case of system breakdown (e.g. power failure, server breakdown, network unavailability…)

- Mobile access point (e.g. tablet PC):

    – Lightweight/portable
    – Easy-to hold / handle and ergonomic design
    – Spill an drip resistant (easy disinfection)
    – Inputs for stylus and touch operation (incl. touch keyboard), "click based input using icons, symbols, …)
    – Wireless communication (immediate access and documentation of patient data)
    – Ease of operation

- Visualisation

    – Different modes of visualisation (chart, table, symbols…) including different relevant parameters
    – Display of several parameters over time in a chart
    – Tabular display: Highlight relevant values
    – Easy to reconfigure (personal configuration)
    – Easy selection of relevant parameters, quick assembling and presentation of data
    – Overview screen "all patient's blood glucose"
    – Parameters ordered hierarchically in individual patient display (with different predefined parameter combinations for medical specialities / diseases …)

- Decision support. Dosing of insulin depends on a lot of parameters which have to be taken into account. This information must be available on one hand on the other there have to be "guidelines" how to titrate insulin. An electronic decision support system (eDSS) could support by "asking the relevant questions" (using the available information) to make a suggestion for insulin dosing.

    – Based on the status of the patient the schedule of blood glucose measurement may change. This means that timing of the measurements varies. An active alarm system would remind the staff to perform measurements/injections
    – Implement a protocol from literature (e.g. RABBIT II trial) and improve
    – visualize "insulin on board"
    – warnings for "insulin on board"
    – alerts for "next insulin administrations"
    – support for calculation of insulin amount depending on known parameters
    – support immediate therapy change (i.e. suggest administration of insulin dose to nurse → the nurse immediately can act within a defined range without involving a doctor + documents what she has done → doctor can control later)
    – flexibility (not a fixed workflow!) – quick response is a very important aspect!

- Data Entry:

    – The system should ask for data entry of relevant parameters and make good guesses on default values (depending on context such as time and previous behaviour…)

- Parameters for documentation (once, at initialisation)
    1. type of diabetes (insulin requirement)
    2. newly diagnosed diabetes
    3. weight/BMI/waist to hip ratio
    4. HbA1c
    5. fever, infection
    6. diarrhoea
    7. hypoglycaemia (last 3 days)
    8. limited renal/hepatic function
    9. pancreas operation

- Parameters required regularly (for decision support)
    1. glucose level (time, trend, last measurement)
    2. injected insulin
    3. food intake / nutrition
    4. classification of the patient regarding insulin sensitive/normal/resistant (subsumes medication, fever, severe of illness, …)

- Quality analysis for ward personnel

    - time within optimal range / acceptable range as quality measure (per patient / for all patients as overview)
- Support identification of "patients at risk" for developing diabetes / need for insulin treatment in the hospital (when they are not on insulin when coming in)

- Automatic transfer of the glucose values to the patient's record/chart: Currently manual transfer of the measured blood glucose values into the patient's record/chart is required although the blood glucose values are stored electronically, which is an error prone procedure.

- Automated transfer of patient related data from the hospital information system

- Automated user identification system to avoid mistakes

- Automated patient identification, when device is close to the bed (RFID, NFC?)

- Archive system: data from former admissions of the same patient can be used for decision making

- The system should be connected to an electronic patient record system so that data which are available elsewhere can be accessed and used for decision making… Therefore standardised interfaces should be available

- Display relevant documents (also medical summary letters) from this patient

- Display / link to evidence based medicine information

- In general, the device should:

    - Not generate additional workload for the staff
    - Reduce cost
    - Improve documentation quality
    - Streamline access to information
    - Enhance security
    - Improve productivity and efficiency
    - Increase accuracy
    - Reduce errors

6.   Trends in Chronic Care (R)evolution

Chronic diseases – such as diabetes, cardiovascular diseases and others – share three important properties: (i) acute and chronic phases alternate during their progress; (ii) their adequate diagnosis and state monitoring require multilevel system biomedical characterization; (iii) their progress may be significantly influenced by the patient's behaviour.

Care for chronic diseases therefore has its own characteristics: (i) it should be continuous, i.e. it should be available and useful between the contact visits and not just during them; (ii) it should be proactive and predictive; (iii) it should influence the patient's lifestyle; and (iv) consist of professional care provided by medical personnel and self-care provided by the patients themselves, moreover self-care accounts for 90-95% of the entire care; (v) the care should be dynamic, meaning all the participants should learn during the care process and correspondingly the care process will be modified.

We believe that inclusion and empowerment of the patient has to be an essential part of chronic care. This is especially true if sustainable healthcare is in focus. In the long term this requires the re-engineering of care and the design and implementation of a new care model.

The main factors shaping the trends in chronic care evolution will be introduced in this section and a care model will be presented that will allow these trends to be implemented.

6.1   Main Factors in Chronic Care

Imagining the future of healthcare and forecasting trends is very complicated, even more so because the European healthcare systemsitself is very complex and it is organised differently in each country. This complexity is illustrated in Figure 17, which shows some of the components that play significant roles in the formation of the trends we are looking for. These factors are several, and include socio-economic, biomedical and clinical R&D, financial incentives (e.g. payment models) and technology development. These factors influence the development and changes in the attitude of the participants of the healthcare system and the changes in the organisations.
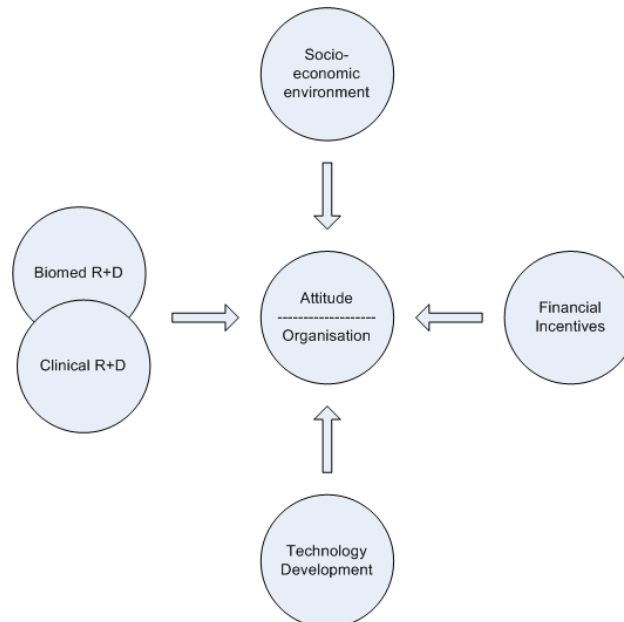
Figure 17 Components in chronic care

Several prediction studies have been published, e.g. by IBM, Intel, PWC and also by health institutions like the NHS, Australian Centre for Health Research (ACHR) etc. See (Intel2007, PriceW2009, Georgeff2007, IBM2006, PriceW2009).

These studies differ in their approach and in the aspects they consider. E.g. Intel and IBM (see (Intel2007), (IBM2006), (IBM2008)) emphasize the technological aspect, whereas PWC (see (PriceW2009), (PriceW2009a), (PriceW2010), (PriceW2010a)) concentrates on healthcare policy. At the same time the NHS and Australian Centre for Health Research (ACHR) (see e.g. (Georgeff2007)) focus on the development of the aspects of health services. However, some important common elements can be extracted from these

approaches. We selected those factors which, in our opinion are significant in the formation of the trends. These factors are:

- Systems biomedicine, an important interdisciplinary area of the biomedical and clinical R&D
- Care space evolution, integrating many different influences
- ICT factor providing information technological ammunition for the development of e-health
- Personalisation, aiming at the individualisation of the care
- Patient focused organisational re-engineering.

Various aspects of these factors have long been in the focus of the R&D activity of consortium members; see (Deutsch2001), (Deutsch2003), (Gergely2001), (Gergely2008). The factors are shown in Figure 18.
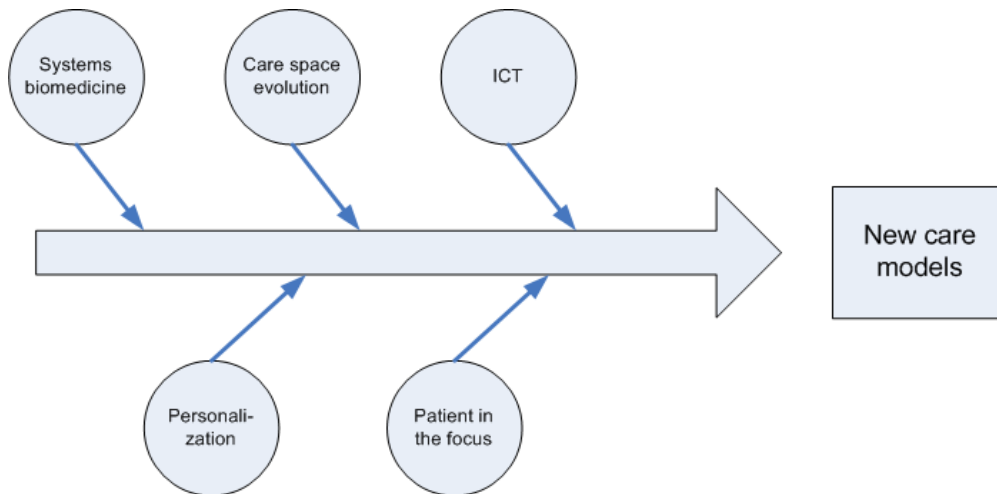
Figure 18 Significant factors in new care models

Systems biomedicine

This provides tools for the development of the individualised physiological model, which permits to realise an efficient risk management. This, in its own turn, helps to realise proactive care. (See Figure 19)
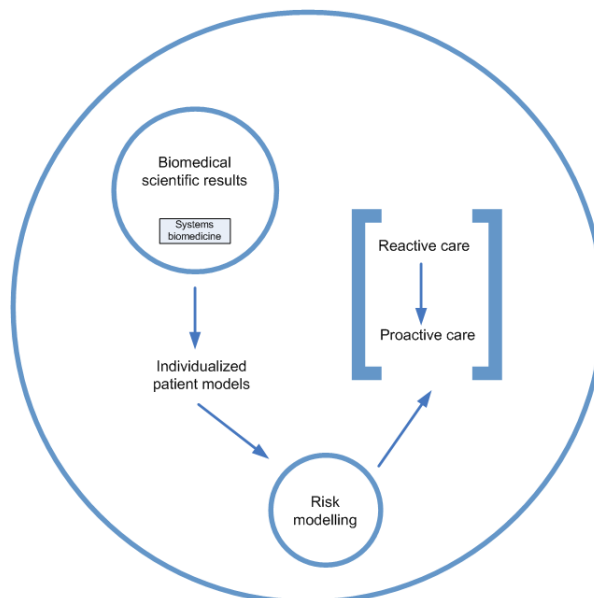
Figure 19 Risk management and proactive care

When healthcare professionals work in an environment where they not only have to care for patients but also have time to think about "their" patients, then proactive care can be achieved.[6]

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[6] http://www.improvingchroniccare.org/index.php?p=The_Chronic_Care_Model&s=2

Care space evolution

Care space evolution results in an explicit space splitting into two interrelated subspaces, the information space and the activity space. Each of these spaces is supported by its own technological developments. Evidences and evidence bases are good examples for an integrated consideration of both spaces, as shown in Figure 20.
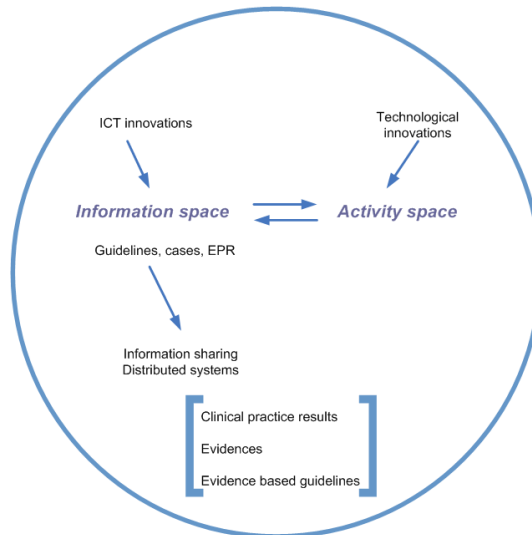
Figure 20 Integration of interrelated subspaces

ICT factor

Here we emphasize the intelligent systems that can provide efficient support for all the participants in the healthcare solution applied. Moreover, another technological development supports the connection of the participants and the development of virtual organisations and distributed systems, see Figure 21.
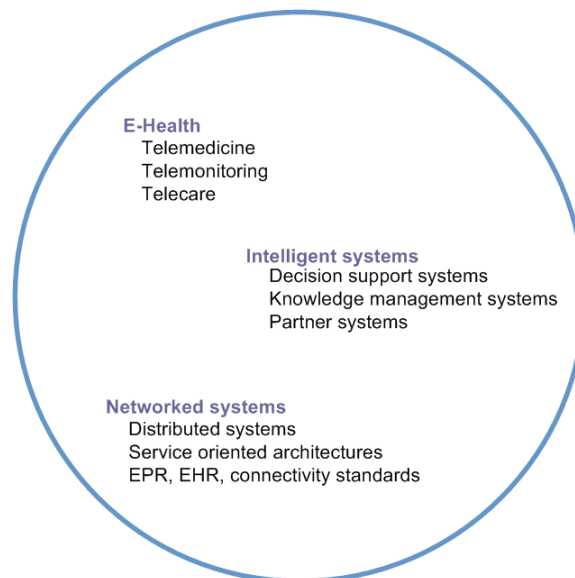
Figure 21 ICT factors

Personalisation

Personalisation has several aspects such as the development of individualised physiological models, selection of personal vital parameters and organisation of their monitoring. Moreover, personalisation may also consider more parameters which refer to e.g. the psychological state of a patient. Personalisation can also be useful in the selection of appropriate communication methods and in the support of concordance, see Figure 22.
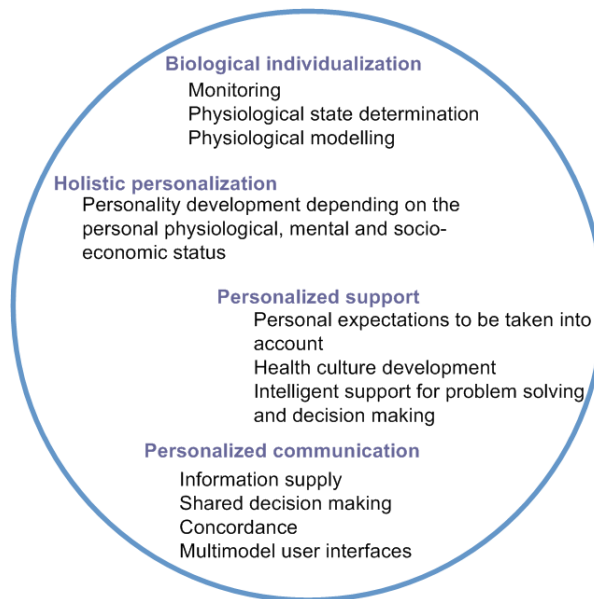
Figure 22 Personalisation

Patient focused organisation

The roles and tasks are distributed among the multidisciplinary health care team members, where the patient has his own self management tasks in an ongoing relationship with the other members of the team. (See Figure 23)
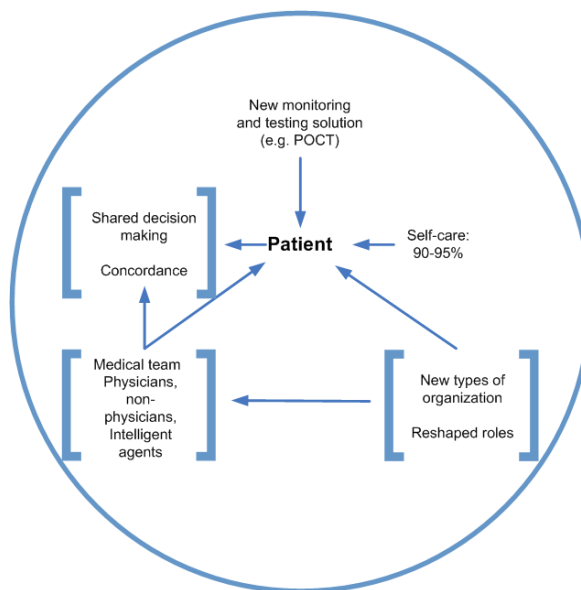
Figure 23 Patient focused organisation

6.2   New Care Models

The trend towards new care models (represented by a wide blue arrow in Figure 18) will lead to important changes in the attitude towards and in the organisation of healthcare.

First we consider the organisational changes, e.g.

- Personalised medicine – personalisation of the care and its person centric realisation

- Patients' participation and empowerment in self-care

- Coordinated integrated and proactive care in a networked model, where each participant is supported

The other result of the trend is the development of attitude. This is illustrated in Figure 24, where we start out from the cost-effective attitude added to it the quality requirements, then enters the evidence based approach, followed by the patient focused approach, and finally the model-based pro-activity appears followed by the appearance of a wider personalisation considering the socioeconomic and cultural factors of the patients' expectations.
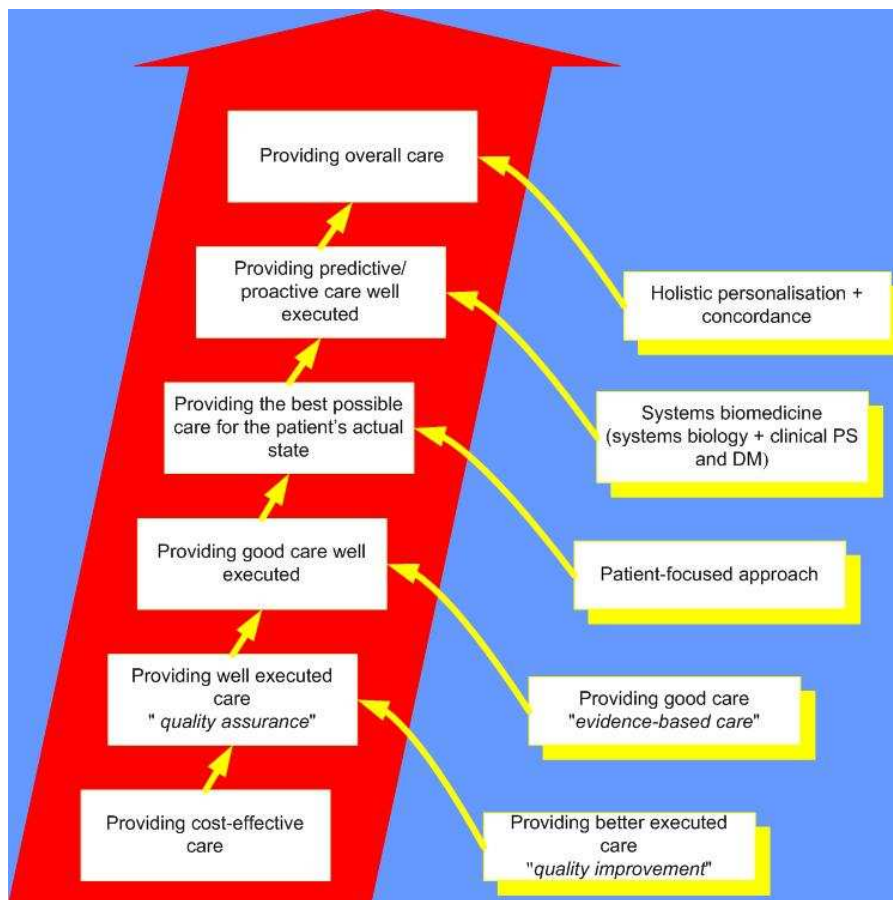
Figure 24 Organisational changes and attitudes

Note that many of these steps are not evolutionary steps forward but rather revolutionary.

How do these changes appear in healthcare practice? They usually appear in an appropriate model of care, which defines the main participants of the care, their relationships and the structure of the care. Moreover, a model of care is also related to care management. (This prescribes application systems, scientific solutions, incentives, and information to improve medical practice and to help patients manage medical conditions more effectively.)

The above trend formulates several required characteristics against a care model, as shown in Figure 25.
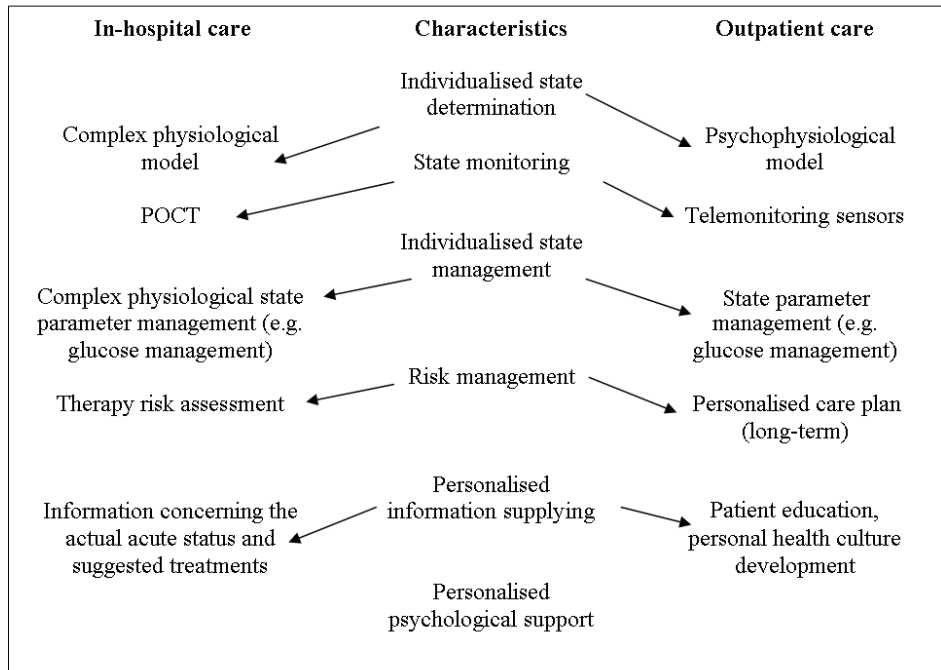
Figure 25 New care model

6.3   Diabetes Care Model in REACTION

A care model becomes manifest at the application layer of the REACTION platform. Its realisation should be supported by the other layers of the platform. That is, care models to be supported formulate requirements against the technological part of the platform. Their implementation permits the support and realisation of the care models, see Figure 26.

The care model described below encompasses the trends outlined earlier. A diabetes care model is introduced, which can be used (i) to identify the workflows of care in REACTION and (ii) to derive the requirements that are necessary to enable the support of the REACTION platform for the applications that are needed for the diabetes care.
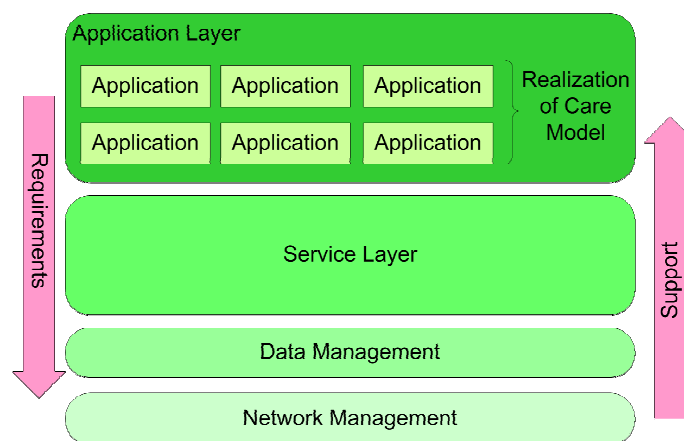
Figure 26 REACTION abstraction levels

The objective of chronic care is to balance the psycho-physiological state of a patient in a constrained optimal interval in order to minimise the risk of appearance of complications and acute phases and to provide a maximally satisfactory life quality for the patient.

The most important requirements for the care can be derived from the above as follows: care should be planned harmonizing with the individual specifics including the following aspects: physiological, psychological, mental, social-economic, worldview and lifestyle.

6.3.1 Personalised Care Plan

The central component of the care is the planning process which provides a personalised plan for each patient. This plan is essential to achieve the above objective. The data for building such a plan are the following: (i) the psycho-physiological status of the patient that can be represented by a model, which may also serve as a basis for the monitoring and control of the care processes; (ii) the psychological, mental, social-economic status of the patient and his/her worldview and lifestyle expectations. A personalized care plan is a complex plan that consists of three main components as it is shown on the following figure.
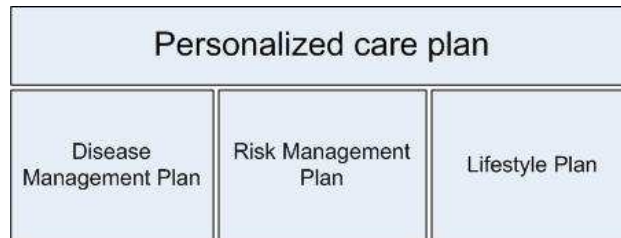
Figure 27 Elements of the outpatient care plan

As Figure 27 shows, the care plan: (i) should be personalized; (ii) should have disease management component, which permits to plan the treatment process focusing on the quality of life and health status optimisation; (iii) should have risk management component, which permits to select the parameters to monitor and plan the corresponding monitoring; and (iv) should have lifestyle planning component that permits to plan patient education and tailor the patient's lifestyle.

The development of the care plan requires up-to-date knowledge of the physicians and other professionals of the team and also the collaboration of the patients and their helpers. Moreover, since the care is dynamic its plan should also be regularly reconsidered. Each care plan requires efficient and complete implementation, which presupposes appropriate organisation of the participants of the care process. This is given by an adequate care model.

In general a model of chronic care is the framework in which the individualized care plan is derived and executed. The care model defines the actors of care, their roles and responsibilities, the possible flow of information and the general flow of the feasible care processes.

The personalised plan should be implemented by the physicians and other professionals (e.g., nurses, nutritionists, and coaches) and patients themselves working together to ensure that patients reach their clinical goals. This implementation requires collaborative work with cooperative problem solving and decision making. Moreover the cooperation presupposes a certain level of concordance between the patient and the medical professionals. The latter requires a certain level of skill from the patient.

The above described requirements against a care model presuppose an effective organisation of the information processes of the care and an efficient intelligent support for all the participants, which can be realised only by the use of efficient info-communication technology. The appropriate implementation of the personalised plan is to be assisted by intelligent computer agents which can provide adequate support for each participant.

An important feature of the proposed care model is that it supports the formation of concordance between the medical team and the patient. This feature is provided by the following properties:

- The model realises a special disease management which takes lifestyle demands and preferences into account and helps making compromises.

- The recommended model combines the evidence-based and the patient-based approach. This means that selecting the appropriate recommendations is not based only on the scientific evidence but also on the patient's individual traits.

- The model suggests a new approach to medical encounters for developing effective treatment planning and disease management.

6.3.2 Information Flows

To establish the care model we first define the two main information flows of the model (see Figure 25.). The first one occurs during the enrolment of the patient to the care. Here, on the bases of pre-processed medical knowledge and through data acquisition with questionnaires and medical examinations the genetic, psychosomatic, socio-economic status of the patient is determined. These, combined with the previously

mentioned pre-processed medical knowledge form the bases of the personalized, disease model. The personalised model includes the behavioural aspects of the patient, e.g. compliance, reminders. Based on the personalized model, forward looking predictions can be formulated providing the bases of the pro-active care. The personalized treatment and intervention plan can be based on the predictions given by the model. Similarly, the personalized lifestyle plan and the personalized monitoring strategy will be built and the patient's physiological status, diet and lifestyle activities will be monitored. The personalized model is regularly updated.
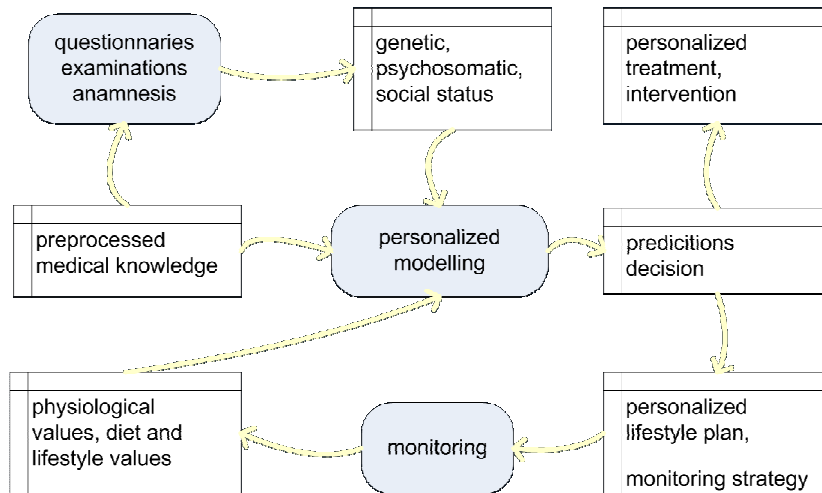
Figure 28 Information flow in the care model

6.3.3 Functional Architecture

The functional architecture of the proposed care model is given in Figure 29.
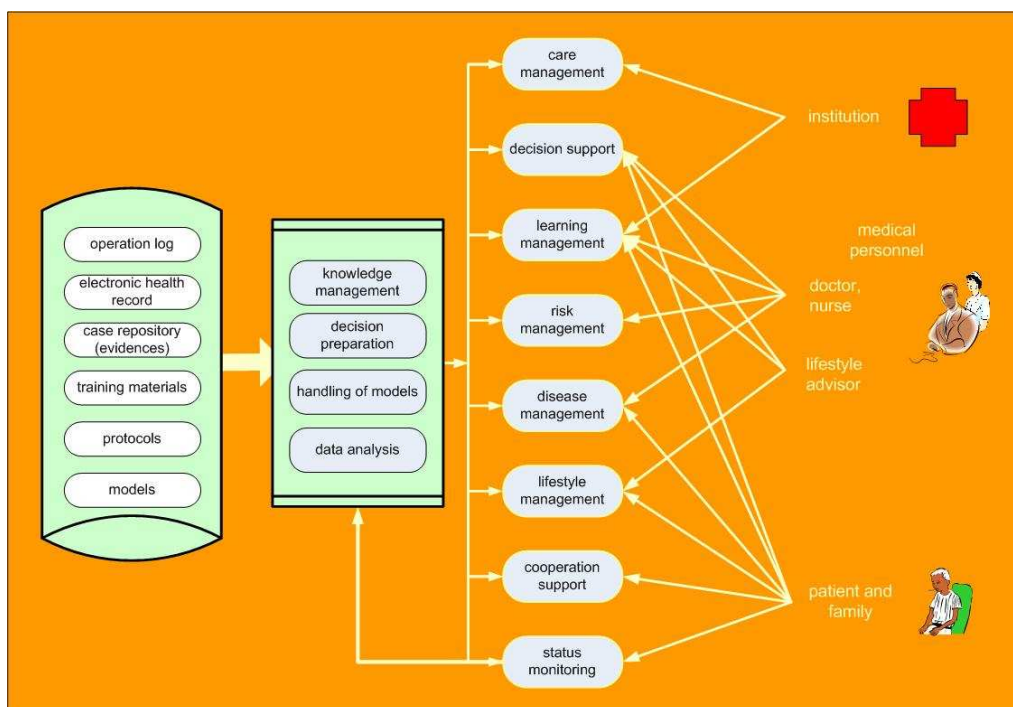
Figure 29 Care model architecture

The main characteristics of the proposed care model are as follow:

- It integrates all participants into a unique virtual organisation. The provided services can be used by all the participants (e.g. physicians, care providers and patients, etc.)

- It provides proactive care based on risk management

- The proposed disease management considers the patient's expectation for his lifestyle and a compromise is suggested between the disease and lifestyle managements

- It combines the evidence based approach with individualisation and patient centric realisation of the care

- It provides a special intelligent agent functioning as a case manager

- It supplies the participants with appropriate information (e.g. physicians have access to the guidelines; the patients can have a look at the problems raised and at their possible solutions). The continuous data and information supply permits the participants to learn from their experience

- It suggests closed loops in the cyclic care processes to improve the efficiency of the care and disease management. The activation and functioning of the loops depend on the patient's health state

- It permits the realisation of an efficient „on demand" visit model

One of the basic pillars of the model is the visit construction. In the suggested model health care is provided in the form of televisits and virtual visits in addition to the contact visits, which are typical in the current chronic-illness management. These visits place patients in a complex health care and social network in which continuous supervision and support are available whenever required. The different services are underpinned by an intelligent information system which supports evidence based medicine and provides pro-active care based on risk management.
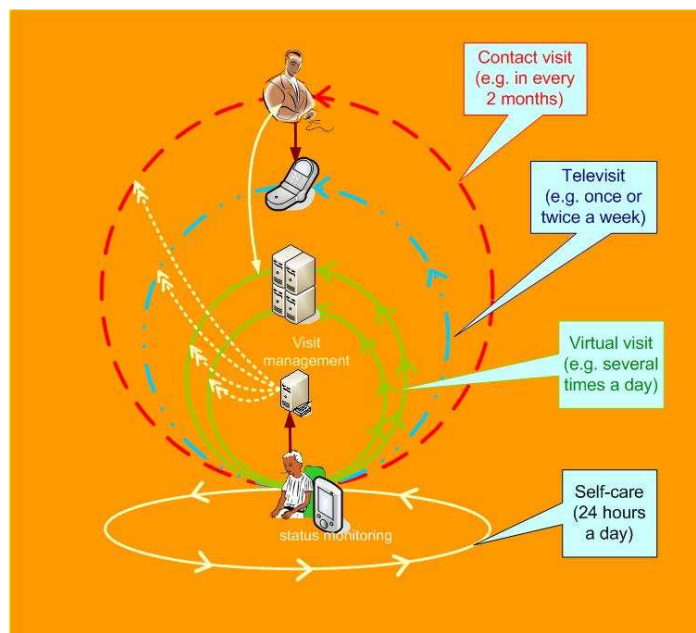
Figure 30 Visit management

6.3.4   In-hospital Care Model

In-hospital care can also be improved by a similar approach. A workflow schema of personalised in-hospital care is shown in Figure 31.
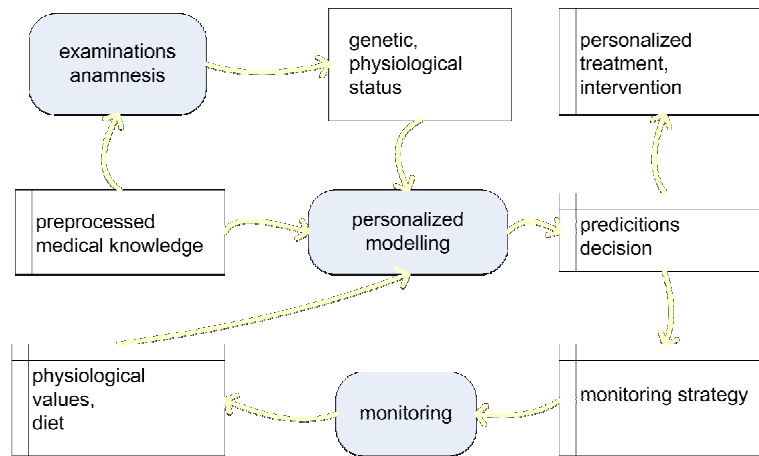
Figure 31 In-hospital care model

7.   Scenario Planning of the Future

The scenario thinking session has been carried out in order to provide the long-term requirements, which should enable and support the full scale future diabetes care model, where inclusion and empowerment of the patient has to be an essential part. Section 7 and section 8 provide an introduction to scenario thinking and the specific methodology called IDON, which has been selected for the REACTION project. Readers familiar with scenario methods can skip these chapters and proceed directly to section 9, where the REACTION scenario process is documented.

7.1   Navigate the Uncertainties of Unknown Futures

Accountable decision-making about future user requirements needs a high element of certainty – an adequate level of knowledge and confidence in our assumptions about that knowledge. But defining user requirements today is far more complex than ever before, taking place in a fast changing, highly uncertain information and technology driven environment. Compounding this, the illusive interlacing of shifting values and policies, social structures and behaviour increasingly undermine predictions on how the future will look. On their own, familiar planning and forecasting practices, which have served us well in the past, cannot deliver the insights and answers we now need.

The process of Scenario Thinking (or Scenario Planning as it is sometimes called) is widely recognized as a tool for creating user requirements specifications under uncertainty.

Scenario Thinking is not about predicting the future and, surprisingly enough, not about choosing the best way forward, though it is indeed a powerful and invaluable tool, which supports this. Its primary value lies in the development of new skills for improving the definition and planning of user requirements.

Developing and deploying these skills enable us to transcend the specific or localised circumstance solution, to go beyond short-term or one-off successes and acquire a consistency and robustness in coherent long-term user scenarios. We come to know the right questions to ask and where to look for missing pieces to the puzzle; how to spot unique opportunities and choose the best way forward

7.2   Context Scenarios

The first step in Scenario Thinking is to fix ourselves firmly in the present. When thinking about the future, we do so within a context; a starting place, or how things are now, give rise to an opening array of ideas or facts, which in turn are related to some sense of a desired goal or objective for future user interaction.

As we convert this information into well-defined stories of possible future situations and what our options for action in them are, we surface the inherent uncertainties that need to be dealt with or overcome. An obvious fact often forgotten is that these uncertainties have sprung out of our original thinking, assumptions, omissions and commissions.

The quality and disposition of original input will strongly influence the flow of thought, handling of material and quality of output. In order to make the best use of scenarios, it is important to clarify our intentions and identify the issues or areas to test with the multiple futures.

7.2.1   What is a Scenario?

The future is awash with uncertainty. Scenarios are snapshots of possible/alternative futures that help us resolve that uncertainty. Scenarios provide coherent, comprehensive, internally consistent descriptions of plausible futures built on the imagined interaction of key trends. It essentially requires you to think from the outside in and takes you through a process that starts with creating context for the unknown.

7.2.2   What is the Purpose?

The purpose of Scenario Thinking is to challenge the preconceived notions that people have of the future, or their maps, and to afford people the flexibility to change those maps. The process is intended to open up the way you think about the future. Scenarios help identify threats, recognize opportunities and make choices about issues of strategic importance. Scenarios illuminate the possible, what might be. It asks you to do something a bit counterintuitive, which is to go beyond the known into the unknown, outside your expertise.

7.2.3   How to Use Scenarios

As you read the scenarios, think about how you might answer each of these questions:

- Is this even remotely possible?

- Would the world be a better place in this scenario?

- If you were a user in this scenario, what would you be doing differently?

- If you knew for sure that this scenario was to come true, what would you as a user do now?

In essence, the Scenario Thinking process is designed to arrive at several parallel hypotheses about the future, which can be held at the same time. These hypotheses are given form and may be pictured by users by embedding them in a story or scenario. In turn, this means that the same person can look at the evidence through different sets of glasses and see things in a different perspective.

7.3   IDON Scenario Thinking

Mapping approaches have received great recognition in the education and business professional activities. Hexagon Mapping is part of a visual facilitation approach, which combines dynamic representation and creativity using visual idea representing units, called IDONS. IDONS afford manipulating, combining and rearranging as a continuous process of formulating thoughts. Hexagon mapping accepts some of the basic theoretical assumptions of system dynamic mapping and the principles of lateral thinking.

Having established the context of investigation, through a variety of information gathering techniques, dialogue and modelling methods, the knowledge is shaped into distinctive alternative stories of the future or scenarios.

IDON Scenario Thinking is based on the logical intuitive story-and-simulation approach to scenario thinking and was originally developed in consultation with Arie de Geus, author of "The Living Company" while head planning coordinator of Shell International.

IDON Scenario Thinking has a well-established track record in a wide variety of fields.

7.4   Development of Scenarios in REACTION

In REACTION, the scenarios will be used to derive detailed user requirements, to investigate the consequences of emerging new or disrupting technologies, as the basis for security and trust analysis and as a model for deriving user validation frameworks.

The scenarios have been developed in a one-day workshop involving a varied group of experts from the domain of diabetes management and therapy. The workshop took place at the Chorleywood Health Centre in the UK. Representatives from partners CHC, FORTH-ICS and IN-JET have facilitated the workshop.

The workshop starts with a short introduction to the REACTION project and an overview of the IDON method for scenario planning.

8.   Implementing the IDON Method

Using the IDON method step by step will result in a set of scenarios that all point to alternative use cases within a given user domain and at a given point in time. All scenarios will have the same frame of reference and – ideally – be equally likely to happen.

The IDON method consists of two parts: Scenario Development and Scenario Deployment. The scenarios are developed in the Scenario Development part using experts and based on knowledge and systematic analysis. The aim is to develop four mind-challenging scenarios by mixing inevitable trends with creative fiction.

In the Scenario Deployment part, technical experts and project decision makers interpret the scenarios and extract a framework for the functional and trust and security requirement specifications. By applying a systematic approach as is used here in REACTION, the interpretation of the scenarios becomes very convincing. The scenario deployment into user requirements takes place in WP3. They become the guiding specifications for the technical development work in REACTION. The validation of the resulting platform will also be linked to the scenarios.

8.1   Creating and Writing Scenarios with a Group

Scenarios are constructed from a varied background of knowledge and guesswork about the relevant environment and the trends and discontinuities likely to happen in the future and affecting the users' business and way of work. The scenarios will draw on both available research and application knowledge in the consortium and on the opinion of a diverse set of experts from different parts of the domain.

The process and group dynamics is managed by a group facilitator, who is also responsible for the final documentation and write-up of the scenarios.

The entire IDON process can be illustrated graphically as in Figure 32.
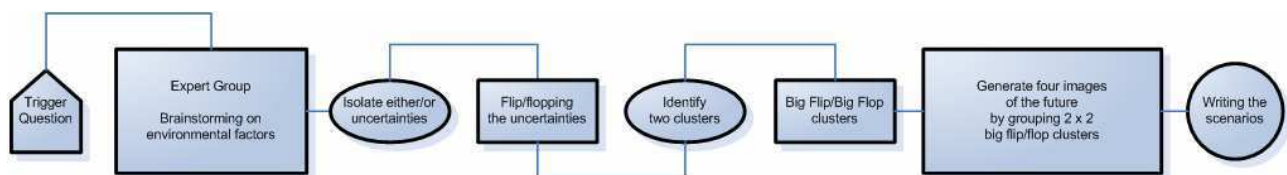
Figure 32 The IDON process

8.2   Environmental Factors

The core of the IDON technique is to examine a set of wider environmental factors, ambiguities and uncertainties identified by the group, in order to resolve which role they are likely to play in the unfolding of a variety of scenarios.

- Some of the environmental factors that might be covered in the discussion process are:
- Research and technology trends
- Institutional and market trends
- Social values and lifestyles
- Economic futures
- Management and delivery systems
- Ethics and values questions
- Global political influences
- Ecological and environmental issues

It can be difficult to move from such a set of factors to actually construct scenarios, but the IDON method and its systematic approach is a good way to do it and has proven its usefulness in many other projects.

8.3   The "Trigger Question"

The initial phase of the IDON method involves three steps. After this phase, a variety of environmental factors will have been identified, evaluated and ranked.

Step 1 – gathering environmental factors

The facilitator formulates a question designed to elicit responses from participants, which will cover the subject under investigation. This is called the "Trigger Question" because it triggers a whole range of creative thoughts about the subject.

Step 2 – positioning on the grid

The next step is to group factors according to their degree of uncertainty and how direct their impact is likely to be on the user domains.

The method is visualised using a conventional two-dimensional grid:
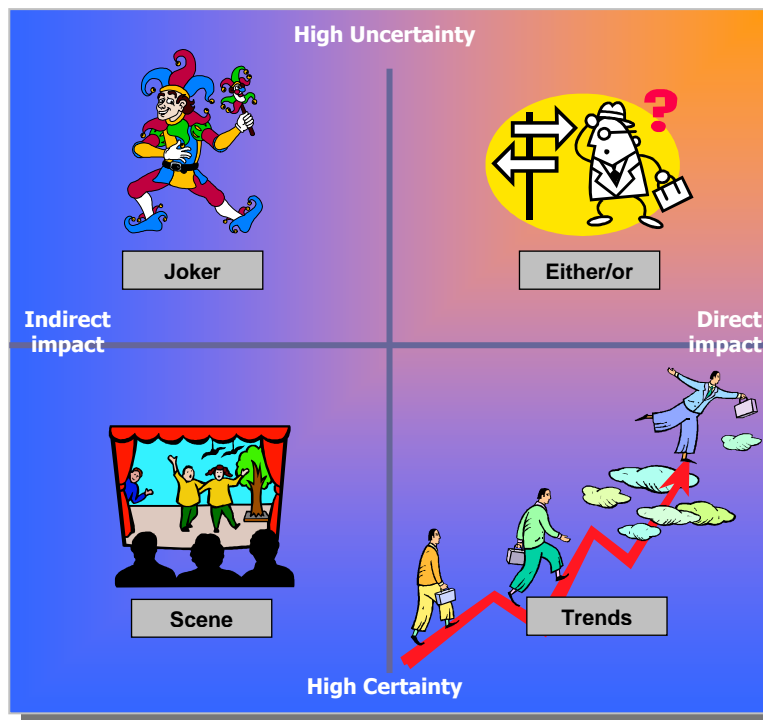
The dimensions of the grid are introduced, without interpretation at this point. The idea here is to begin to sort the different factors, placing them on the grid, where the participants feel they best belong. Each factor is taken in turn and its position discussed and provisionally fixed according to its perceived "Higher" or "Lower" degree of uncertainty and "Indirect" and "Direct" impact in the user cases. Note that absolute positioning is not the point; it is the relative positioning that is important.

Step 3 – Survey all factors

When all the factors have been placed in position, the whole set is reviewed by the group and fine adjustments is made in relative positioning.

8.4   Characterisation of the Quadrants

Each quadrant has a different interpretation, but there is no sharp line of distinction either vertical or horizontal. The behaviour of each group of factors in broad terms is as follows:

Top - right: Pivotal uncertainties (Either/or)

These factors are likely to have a direct impact on the user cases, but their outcome is uncertain.

They are pivotal in the sense that the way they turn out may have strong directional consequences.

These factors will determine the shape of the different scenarios.

Top - left: Potential jokers (Joker)

These factors are rather uncertain as to their outcome and maybe also less relevant to the user cases. However, it could be dangerous to treat them as merely noise. They represent factors that should be monitored in case they move strongly to the right, i.e. develops a direct impact on the user cases.

<u>Bottom - right: Significant trends (Trends)</u>

These factors impact more directly on the user cases and it should be possible to anticipate their effect.

<u>Bottom - left: Context shapers (Scene)</u>

These are relatively certain factors and are bound to shape the future context

8.5   Use of the Quadrants

In the scenario building we are going to explore the uncertainties from the "Either/or" quadrant to derive a set of different scenarios for the user cases. Each scenario will thus reflect the uncertainties attached to the environmental factors grouped in this quadrant.

The environmental factors grouped in the other quadrants will be retained for reference and inclusion in the final stage of writing up the scenarios in the following ways:

The factors in the context shapers quadrant are those that should be woven into every scenario, if it is written up fully. These factors will be used to describe a common scene for all scenarios.

The significant trends will also be found in each scenario, but the manner in which they manifest themselves will be different. The factors in this quadrant can be said to constitute different sets placed on the scene.

The potential jokers are useful factors to bring into the scenarios during the process, if the scenarios are starting to become too uniform.

A further description of the use of the various quadrants will be given in each of the REACTION user cases.

8.6   Creating Prototype Scenarios

Scenarios can be thought of simply as having three levels. At base level there are the context shapers, which seem fairly inevitable and will tend to underpin all scenarios at a given time – these are changes that are common throughout, like the stage in a theatre.

At the intermediate level there are trends, which can be quite complex because of the variety of ways they can interact with each other. These will be modified from scenario to scenario, but still retain their basic condition. These can be likened to the changing scenery in a play.

At the differentiated level each scenario has some unique variances. These differences arise from the uncertainties we perceive. An uncertainty about something means that at least things could go this way or go the other way. Uncertainties may be mainline or they may be jokers.

As these uncertainties interact in different ways that affect how things turn out, the number of combinations of even twenty variables is enormous. We need a way to simplify this information, without diluting its impact, into different emergent stories of the future. These may be perceived as the different dramas that might be put on in a theatre. In order to do this we go through the following stages in creating prototype scenarios from which a full set of scenarios can be developed.

We have chosen here a way to generate four contrasting scenarios. The purpose of this technique is to create simple scenarios that bring out distinct future challenges. At the end of the Scenario Development phase, one of the scenarios will be chosen for implementation as the REACTION user scenario in the respective user area.

Arriving at the prototype scenarios involve three steps.

Step 1 – Rephrasing the Pivotal Uncertainties as Questions

Looking at the factors in the quadrant marked "Either/or", participants are invited to think of each one as an uncertainty question for which there are two possible outcomes. We will call one outcome state the "flip" (e.g. Yes, education will be affordable) and the other contrasting outcome state the "flop" (e.g. No, education will not be affordable). When the factor in question has either "flipped" or "flopped", the uncertainty is resolved.

An example may illustrate the technique. Assume that the group is working on writing scenarios in a teaching environment. The group has identified a number of uncertain environmental factors (listed in column 1 in the table below). For each factor, a flip (+) and a flop (-) question is formulated (column 2).

Price of education How will the price of education develop in the future?	+	Education will continue to be affordable
	-	Education will become relatively more expensive than today
Access to information How accessible will information be?	+	Easy access to information
	-	Difficult to get access to information
Media types Which media type will proliferate?	+	Electronic media dominate
	-	Traditional media will be retained
Mobility How will people move around?	+	Commuting will be increasingly difficult
	-	Mobility will increase
Equipment Will people have access to the necessary equipment?	+	Access to learning equipment is facilitated
	-	Equipment is only available to few
Learning method What will be the dominant learning method?	+	Emphasis on individual learning
	-	Emphasis on shared learning
Organizational learning How will organizational learning evolve?	+	No take-up of organizational learning
	-	Adoption of organizational learning
Collaboration Will people collaborate with co-workers?	+	Minimal collaboration
	-	Collaborative thinking at work
Feedback What kind of feedback is available?	+	Poor feedback system
	-	Good feedback system
Global pressure How will the global pressure develop?	+	Global pressure reducing
	-	Global pressure for "best in class"

Step 2 – Grouping the factors

The group will now search for connections and associations between the various factors (uncertainties). Uncertainty areas connect because of the impact of their influence of each other, either because if one "flips" the other will "flop" or because they are likely to align by association.

This is a kind of domino effect. The group will continue to work with the associations, until there are two main clusters or at least two priority clusters out of a set.

In the example above there are 10 environmental factors (uncertainties) of which the first 5 have to do with how people will approach learning ("Learning Location"). The remaining five can be said to relate to the "Learning Culture".

Step 3 – Naming the subplots

In the clusters we now have groups of questions. When one of the uncertainty questions resolves to, say, a "flip" side, it will tend to correlate with the "flip" side of all the other uncertainties in that cluster. This will end up resolving the entire cluster as a large scale "flip" or "flop". It is rather like a group of little magnets organizing themselves to a main north pole and south pole. The two outcomes of the whole cluster are called subplots, which will combine in different ways according to the "flip/flop" questions to give us different scenarios.

In the example we can now group the uncertainties in the "Learning Location" cluster as big "flips" and "flops":

Big Flip Cluster "Learning Location"	Big Flop Cluster "Learning Location"
• Education affordable • Easy access to information • Electronic media dominate • Commuting increasingly difficult • Access to learning equipment leads to the name: REMOTE LEARNING	• Education will be expensive • Difficult to access information • Traditional media retained • Mobility will increase • Equipment only for the few leads to the name: LOCAL LEARNING

In a similar way we can group the "learning culture" cluster:

Big Flip Cluster "Learning Culture"	Big Flop Cluster "Learning Culture"
• Emphasis on individual learning • No up-take of organizational learning • Minimal collaboration • Poor feedback system • Global pressure reducing leads to the name: INDIVIDUALISM DOMINATES	• Emphasis on shared learning • Adoption of organizational learning • Collaborative thinking at work • Effective feedback system • Global pressure for "best in class" leads to the name: CORPORATISM DOMINATES

Each name needs to express a coherent alternative view of the combined uncertainties – more than simply "good" or "bad" but suggestive of how things might develop. They should be imaginative and evocative, like good chapter headings of a novel, and easy to remember, because throughout the project, the names will be used to quickly identify a tremendously complex set of future uncertainties in a large number of environmental factors.

8.7   Generating Multiple Images of the Future

When the subplots have been generated using the "flip-flop" method, they need to be combined to form scenario structures. On the one hand this is a logical process in which there are a set number of combinations statistically. On the other hand it is an intense exercise of imagination and judgment, where the participants are challenged to synthesize each set of combinations to formulate scenario stories, which are stimulating and relevant to the thinking task.

The purpose of this is to arrive at creating four scenarios generated from the two clusters, each of which has two states or subplots. The titles of these scenarios will represent four distinct possible futures extrapolated from the thinking done by the group and will hold rich meanings, which can be further fleshed out when the scenarios are written up after the exercise is completed.

The four outcomes from the two clusters can be combined in four different ways to form images of the future. In our example the possible combinations are as follows:

1. Remote Learning + Individualism Dominates

2. Remote Learning + Corporatism Dominates

3. Local Learning + Individualism Dominates

4. Local Learning + Corporatism Dominates

The group members now use their imagination to form a mental picture of the world that emerges within each of the four combinations and formulate a provisional title for that world. The result will be presented in a two-dimensional grid like this:

8.8   Writing up Scenarios

At the end of the exercise the scenarios are written based on the group discussions and the imaginations and visions created during the workshop. Group members usually perform the writing up of the stories after the workshop.

Step 1 – Development of the scene

When a scenario is written, the writers start with the scene, which is common for all scenarios. The elements for defining the scenes are found in the lower left "Scene" quadrant of the original grid of environmental factors. The scene must reflect the basic characteristics of the user area, for which the scenarios have been developed.

Step 2 – Building the set

The environmental factors in the lower right "Trend" quadrant constitute the changing sets that are built on the scene for each scenario. Trends have a direct influence on the story in the scenario, but only the environmental factors that are relevant to the scenario are used.

Figure 33 Four scenarios

Step 3 – Defining the script

In the final step, the story is written from the prototype scenario so that the scenarios come to life as imaginative plays.

In writing the scenarios, it is useful to let the environmental factors enter the scene, set or script according to a simple grouping:

What is happening?

How is it happening?

Why is it happening?

The final scenarios are illustrated with pictures to stimulate the reader's imagination.

9.   REACTION Vision Scenarios

A vision scenario workshop was held on April 30th 2010 at the Chorleywood Health Centre, North West of London.

Ideally, in order to have a wide spread in expertise and experience, at least one representative of each of the following groups of experts was envisaged: Doctors, nurses, health economists, patient organisations, ICT specialists.

However, on relatively short notice, it was not possible to cover all these areas, The following persons from outside the REACTION project participated:

- Mrs Rajula Dodia, pharmacist
- Mr Hitash Dodia, pharmacist
- Mr Richard Foggie, BIS, Assistant Director, Electronics Innovation, EITSU
- Miss Linda Hands, Consultant, Vascular Surgery and Telemedicine
- Mr George MacGinnis, Communication for Health Innovation team, NHS Tech Office

As experts in their fields Dr. Russell W. Jones and Joanna Fursse of CHC and Malcolm Clarke of UBRUN also participated in the discussions about the potential influences of the environmental factors listed in Section 9.3.

Though on the surface the expert group lacked cross-European participation, it is generally agreed among the clinical partner members that diabetes management and therapy is very similar in the EU member's states, and indeed in most of the world.

The vision scenario workshop was carried out by partners CHC, UBRUN, FORTH-ICS and IN-JET, with CHC offering to host the event and together with UBRUN liaising with external experts. ALL contributed a presentation on new care models, outlined in Section 6. FORTH-ICS and IN-JET participated as moderators and facilitators. The scenarios were later developed by IN-JET, and the results presented in Section 10.

9.1   Selection of Clinical Domains and Timeframe

The focus of the first part of the REACTION project will be the development of a remotely accessible healthcare network with sensor technology and devices aimed at supporting and improving remote monitoring in existing case management workflows. Later in the project the aim will be extended to cover future workflows and new care models for the same groups of patients.

A relatively long-term timeframe (year 2020) was set for the project, which participants felt was suitable when discussing future trends and developments in the domain of diabetes management and therapy.

9.2   Trigger Question

The "Trigger question" for identification and grouping of environmental factors is thus:

> How do we perform chronic disease management and therapy using intelligent networked medical devices in 2020 and beyond?

9.3   Identification of Environmental Factors

Environmental factors from the following areas were identified as possible influences on chronic disease management in 2020:

- Clinical and medical trends
- Market trends
- Economic and resource futures
- Social values and lifestyles

- Technology trends
- Ethical and value questions
- Global healthcare policies

Below we present the results of the brainstorming discussion, summarise the items of both certainty and uncertainty identified by the experts as well as the subsequent analysis and clustering performed afterwards.

The workshop participants defined a total of 66 factors in all areas:

Clinical and medical trends (C)
Psychosomatic illnesses
Predictive and proactive care
Cure for diabetes
Professional barriers
Personalisation
Multi-disciplinary agile teams
On-demand visit
Patient information exchange
Integrated multi-disciplinary teams
Co-morbidity
Focus on multiple chronic illnesses
Genetic diagnosis
Disease management
Redefining illnesses
Integrated and holistic care delivery
Decentralised care
Non-hospital healthcare delivery
Effectiveness of drugs
Patients want seamless healthcare

Market trends (M)
Wellness support by insurance companies
Counterfeit drugs
Wellness is a growing market
Manufacturers move towards a patient centric approach

Economic and resource futures (€)
Payment by result
Personal health budgets
High costs vs. yield
Public funding of healthy lifestyle
Discarded medicine
Financial pressures
Increasing cost of new drugs and procedures
Cost effective care
Less resources for healthcare

Social values and lifestyles (L)
Patient-2-patient support
Lifestyle management
Auto-diagnosis
Social pressure
Education
Self-management
Patient expectations
Focus on lifestyle

Technology trends (T)
RFID in pills for treatment compliance
State monitoring
Adaptable technology
Adherence and compliance
Concordance
Virtual teams
Visit management
Risk assessment
Intrusive healthcare ICTs
Holistic telemedicine
Protection of patient privacy and data
Telemedicine
Monitoring
Drug tracing
Closed-loop management

Ethical and value questions (V)
Patient privacy rights
Liability
Internet access a Human Right
Trust
Legal issues

Global healthcare policy influences (G)
Socialised medicine
New care models
Social care vs. healthcare
Retirement age
More people chronically ill
Ageing population

The environmental factors were then grouped according to the certainty and impact criteria, which yielded the following matrix:

High UNCERTAINTY

Joker

Either/or

T Holistic telemedicine

L Patient-2-patient support groups

€ Public funding of healthy lifestyles

€ Personal health budget

€ Payment by results

T Visit management

L Auto-diagnosis

T Virtual teams

T State monitoring

T Adaptable technology

T RFID in pills for treatment compliance

L Social pressure

M Wellness support by insurance companies

C Integrated multi-disciplinary teams

L Lifestyle management

T Adherence and compliance

T Risk assessment

G New care models

T Concordance

C Psychosomatic illnesses

C Patient information exchange

C Predictive and proactive care

T Intrusive healthcare ICTs

G Socialised medicine

C Professional barriers

C On-demand visits

C Cure for diabetes

C Personalisation

C Multi-disciplinary agile teams including patients

€ High costs vs. yield

Indirect Impact

Direct Impact

€ Discarded medicine

L Patient expectations

€ Financial pressures

L Focus on lifestyle

C Decentralised care

C Effectiveness of drugs

V Trust

C Redefining illnesses

C Genetic diagnosis

V Patient privacy rights

C Patients want seamless healthcare

V Legal issues

C Focus on multiple chronic illnesses

M Wellness is a growing market

T Protection of patient privacy and data

T Drug tracing

T Closed-loop management

G Social care vs. healthcare

G More people chronically ill

C Disease management

V Liability

T Monitoring

€ Less resources for healthcare

L Self-management

G Ageing population

V Internet access a Human Right

€ Cost effective care

M Manufacturers move towards a patient centric approach

G Retirement age

C Non-hospital healthcare delivery

€ Increasing costs of new drugs and procedures

L Education

M Counterfeit drugs

T Telemedicine

C Integrated and holistic care delivery

C Co-morbidity

Scene

Trends

High CERTAINTY

9.4   Flip-Flopping the Pivotal Uncertainties

Looking at the marked factors in the "Either/Or" quadrant we group them in clusters. Each of the clusters will form different scripts in our scenarios. We now consider the uncertainties as a question, for which there are two possible outcomes: the "flip" (+) and the "flop" (-) outcome. When the factor in question has either "flipped" or "flopped", the uncertainty is resolved. The following table presents all the uncertainties (21 in total) in the Either/Or quadrant and the related flip-flow questions.

Predictive and proactive care Will predictive and proactive care be prioritised?	+	There is an explicit priority of and focus on providing predictive and proactive care with the particular aim of preventing chronic diseases and their associated long-term complications.
	-	There is no particular priority of or focus on providing predictive and proactive care nor are there any explicit aims to prevent chronic diseases and their associated long-term complications.
Visit management Will contact visits be supplemented by virtual visits and televisits?	+	ICT systems support virtual visits and televisits in addition to contact visits
	-	ICT systems do not support virtual visits and televisits
Payment by results Will healthcare professionals get paid according to the results of the care they provide?	+	A scheme based on the results of the provided care determines the rate paid to healthcare professionals.
	-	Healthcare professionals get paid independently of the results of the care they provide.
State monitoring Do innovative ICT solutions enable monitoring of vital parameters defining the overall state of the patients?	+	Innovative ICT solutions monitor vital parameters defining the overall state of the patient.
	-	ICT solutions only monitor blood glucose.
Risk assessment How big a role will risk assessment results play in the management of chronic diseases?	+	Risk assessment is an integral part of chronic disease management and therapy.
	-	Risk assessment only plays a minor role in relation to chronic disease management and therapy.
Wellness supported by insurance companies Will insurance companies actively support wellness and prevention initiatives?	+	Insurance companies see clear advantages in supporting wellness and prevention initiatives.
	-	Insurance companies are not interested in supporting wellness and prevention initiatives.
Patient-2-patient support groups Will patients rely on additional advice and support from fellow patients?	+	Patients increasingly rely on patient-2-patient support groups for additional advice and support on how to live with and manage their disease.
	-	Patients do not rely on patient-2-patient support groups for additional advice and support on how to live with and manage their disease.
Social pressure Will there be increasing social pressure to adopt a healthy lifestyle?	+	Social pressure and seeking social acceptance motivates many people to lead healthier lives
	-	There is no social pressure in relation to healthy/unhealthy lifestyle choices.
Intrusive healthcare ICTs Will patients fear that healthcare ICTs will be too intrusive?	+	Patients are positive about healthcare ICTs and feel that they can help them to lead a normal active life with their condition.
	-	Patients are sceptical about healthcare ICTs and feel that they are too intrusive and threaten to take over their lives.
Concordance Are patients involved in decision-making to improve their compliance with medical advice?	+	Patients are always involved in the decision-making regarding the course of treatment or care.
	-	Patients are not involved in the decision-making regarding treatment procedures or care.

Adherence and compliance Will ICT solutions support patients in adhering to and complying with medical advice and treatment procedures?	+	ICT solutions support patients in adhering to and complying with medical advice and treatment procedures.
	-	ICT solutions do not support patients in adhering to and complying with medical advice and treatment procedures.
Patient information exchange Will different healthcare professionals exchange information about their patients?	+	Healthcare professionals make sure to exchange information about their common patients.
	-	Healthcare professionals do generally not exchange information about their common patients.
Socialised medicine Is healthcare publicly or privately funded?	+	Healthcare is mainly publicly funded.
	-	Healthcare is mainly privately funded.
New care models Are new care models in place that affects healthcare policies?	+	New care models are being employed which affect healthcare polices.
	-	No changes are made to existing healthcare models.
Professional barriers Will barriers between healthcare professionals become less rigid resulting in more shared or overlapping tasks and responsibilities?	+	Barriers are broken down and tasks and responsibilities are increasingly overlapping and shared between different groups of health professionals.
	-	Barriers are rigid different groups of healthcare professionals are assigned clearly defined tasks and responsibilities.
High costs vs. yield Will the expected yield of certain medical procedures and therapies justify their costs?	+	The expected yield of medical procedures and therapies will override concerns about costs.
	-	Concerns about costs as compared to the expected yield limit which medical procedures and therapies are offered.
Personalisation Will healthcare become more personalised?	+	Healthcare is becoming more and more personalised and adapted to each patient's specific situation and personality.
	-	Healthcare is very generic and does not consider individual patients' situations or personalities.
Public funding of healthy lifestyle Will certain initiatives to live a healthier life, such as joining gyms, sports clubs and weight loss groups, be included in public healthcare funding?	+	Public healthcare funds also cover the costs of healthy lifestyle initiatives.
	-	Public healthcare funds do not cover the costs of healthy lifestyle initiatives.
Multi-disciplinary agile teams including the patient Will healthcare professionals and patients form agile multi-disciplinary teams?	+	Multi-disciplinary agile teams including the patient are used in healthcare.
	-	Multi-disciplinary agile teams including the patient are not used in healthcare.
Personal health budget Will public healthcare be based on a "personal health budget" model?	+	Public healthcare is not based on a personal health budget model but provides healthcare as needed for all.
	-	Public healthcare is based on a system where citizens have been allocated a personal health budget.
Adaptable technology Will ICT solutions be sufficiently adaptable to match the future complexity of chronic disease management?	+	Adaptability of ICT solutions will match the complexity of chronic disease management.
	-	ICT solutions will not be sufficiently adaptable.

Table 3 Uncertainties and related flop-flop

9.5   Clustering the Uncertainties

We now group the pivotal uncertainties into two groups, or clusters, by searching for connections and associations between the various uncertainties. Within a cluster, uncertainties tend to counter align in flip-flop questions so that if one flips, the other will flop.

In inspecting all 21 uncertainties it becomes obvious that they can be separated into two distinct groups. One group of uncertainties is related to the way healthcare is delivered, in which spaces and subspace it is delivered and to the patients' role in each subspace. This cluster of uncertainties has been named "**Care Space**".

The other group of uncertainties is related to the financial resources and other constrains placed on the health care models such as social, ethical and cultural values, and how these affect the nature and priorities of healthcare provides. This cluster has been named "**Driving Force**".

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Care Space

- Predictive and proactive care
- Visit management
- State monitoring
- Risk assessment
- Intrusive healthcare ICT
- Adherence and compliance
- New care models
- Professional barriers
- Patient information exchange
- Personalisation
- Multi-disciplinary agile teams incl. the patient
- Adaptable technology

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Driving Force

- Payment by results
- Wellness support by insurance companies
- Patient-to-patient support groups
- Social pressure
- Socialised medicine
- High costs vs. yield
- Public funding of healthy lifestyle
- Personal health budget
- Concordance

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9.6   Naming the Subplots

Having identified all the flip-flop questions and grouped the uncertainties in two clusters, we are now ready to perform the last step before scenario write-up, i.e. naming the different subplots that will define the scripts.

In the clusters we now deploy the flip-flop questions from above. We analyse and group the responses thus resolving one entire cluster into a large-scale flip or a large-scale flop. We do this for both clusters.

In the "**Care Space**" cluster, we arrive at a large-scale flips and flops as shown in the table below.

The *big flip* cluster of **Care Space** describes a healthcare system where prediction, prevention and integrated healthcare are key words. Healthcare professionals work across professional barriers and patients are actively engaged in defining their own care. Healthcare is thus highly personalised and delivered in distinct spaces to optimise the impact. ICT is actively deployed to further support this care model and support patients in effectively managing their disease. ICT also facilitates communication between different groups of healthcare professionals.

In contrast, the *big flop* of the **Care Space** cluster describes a situation where the healthcare system is very conservative and fails to adapt to patients' individual health needs and problems. There are rather strict boundaries between different healthcare professionals and their roles and tasks. Exchanging information about the patient is generally not practised. Although ICT are available they are not used to improve communication or to support patients in self-management and compliance.

Big Flip Cluster – "Care Space"	**Big Flop Cluster – "Care Space"**
• There is an explicit priority of and focus on providing predictive and proactive care with the particular aim of preventing chronic diseases and their associated long-term complications.	• There is no particular priority of or focus on providing predictive and proactive care nor are there any explicit aims to prevent chronic diseases and their associated long-term complications.
• ICT systems support virtual visits and televisits in addition to contact visits	• ICT systems do not support virtual visits and televisits
• Innovative ICT solutions monitor vital parameters defining the overall state of the patient	• ICT solutions only monitor blood glucose
• Risk assessment is an integral part of chronic disease management and therapy	• Risk assessment only plays a minor role in relation to chronic disease management and therapy
• Patients are positive about healthcare ICT and feel that they can help them to lead a normal active life with their condition.	• Patients are sceptical about healthcare ICT and feel that they are too intrusive and threaten to take over their lives
• ICT solutions support patients in adhering to and complying with medical advice and treatment procedures.	• ICT solutions do not support patients in adhering to and complying with medical advice and treatment procedures
• New care models are being employed which affect healthcare policies.	• No changes are made to existing healthcare models
• Barriers are broken down and tasks and responsibilities are increasingly overlapping and shared between different groups of healthcare professionals	• Barriers are rigid different groups of healthcare professionals are each assigned clearly defined tasks and responsibilities
• Healthcare professionals make sure to exchange information about their common patients	• Healthcare professionals do generally not exchange information about their common patients
• Healthcare is becoming more and more personalised and adapted to each patient's specific situation and personality	• Healthcare is very generic and does not consider individual patients' situations or personalities
• Multi-disciplinary agile teams including patients are used in healthcare.	• Multi-disciplinary agile teams including patients are not used in healthcare
• Adaptability of ICT solutions will match the complexity of chronic disease management.	• ICT solutions will not be sufficiently adaptable
which leads to the name:	*which leads to the name:*
Proactive Healthcare	**Conservative Healthcare**

Similarly, in the "**Driving Force**" cluster, we arrive at the following large-scale flips and flops:

In the *big flip* **Driving Force** cluster, financial incentives are optimised and used to promote healthy living and in providing the most effective care to patients; benefits are sometimes prioritised over costs but patient involvement can be actively used to reduce costs in other areas. Healthcare is publicly funded and even some lifestyle initiatives are publicly funded. As there is great social pressure on people to adopt healthy lifestyles, insurance companies have found a new market in offering insurance to support wellness and prevention initiatives. Also, patients increasingly use patient-to-patient groups to support them in dealing with their disease in a cost effective way.

ICT facilitates - and thus improve - communication between healthcare professionals and patients

In the *big flop* **Driving Force** cluster, financial issues have an immense influence on the extent of treatment and therapy that are available and cost effectiveness is always the priority. Costs weigh higher than benefits and healthcare provision is based on a result-oriented principle where healthcare professionals are paid according to the results they achieve, i.e. healthy patients. Public healthcare tends to be increasingly privately funded (including co-payments) and the publicly funded healthcare may be based on a personal health budget for life, which basically means that there is a set limit to how much a person "can cost" public healthcare over a lifetime. Even so, insurance companies do not see any potential benefit in supporting wellness and healthy living.

Generally, communication of incentives to support and encourage healthy living is lagging; healthy/unhealthy lifestyle is an individual choice and thus hasn't as yet become integrated into dominant social and cultural values and norms. Also, patients are not involved in any decision making processes regarding their care and patients are generally rather detached and disengaged. Moreover, as patients generally don't look to patient-to-patient groups for additional and self-management is far from becoming effective.

Big Flip Cluster – "Driving Forces"	Big Flop Cluster – "Driving Forces"
- A scheme based on the results of the provided care determines the rate paid to healthcare professionals - Insurance companies see clear advantages in supporting wellness and prevention initiatives - Patients increasingly rely on patient-2-patient support groups for additional advice and support on how to live with and manage their disease. - Social pressure and seeking social acceptance motivates many people to lead healthier lives - Healthcare is mainly publicly funded - The expected yield of medical procedures and therapies will override concerns about costs - Public healthcare funds also cover the costs of healthy lifestyle initiatives - Public healthcare is not based on a personal health budget model but provides healthcare as needed for all. - Patients are always involved in the decision-making regarding the course of treatment or care.	- Healthcare professionals get paid independently of the results of the care they provide - Insurance companies are not interested in supporting wellness and prevention initiatives - Patients do not rely on patient-2-patient support groups for additional advice and support on how to live with and manage their disease - There is no social pressure in relation to healthy/unhealthy lifestyle choices - Healthcare is mainly privately funded - Concerns about costs as compared to the expected yield limit which medical procedures and therapies are offered - Public healthcare funds do not cover the costs of healthy lifestyle initiatives. - Public healthcare is based on a system where citizens have been allocated a personal health budget for life. - Patients are not involved in the decision-making regarding treatment procedures or care
which leads to the name:	*which leads to the name:*
Patient-centric	**Cost-focused**

9.7   Multiple Images of Chronic Disease Management and Therapy in 2020 and Beyond

We are now able to define the structure of the scenarios by looking at all the environmental factors in the matrix.

9.7.1   Developing the Scene

We find the environmental factors that make up the scene in the lower left quadrant of the grid. These factors are considered to be rather certain and are thus common for all the scenarios.

Some of the scene factors here are related to demographic and health factors, such as an ageing population and an increase of people with chronic diseases. In concordance with these factors, the structure of healthcare delivery, disease management, and financial issues are important for setting the stage.

We also see that wellness is a growing market and that illnesses are being redefined in line with health and healthcare developments. Also, patients have rights and demands and they expect proper and appropriate care. The continued development of ICT, the use of telemedicine and the digitalisation of the society bring up new legal and ethical issues such as security and privacy and access to the Internet.

9.7.2   Building the Sets

The environmental factors in the lower right quadrant, the Trends, constitute the changing sets that are built into the scene for each scenario. Several trends were identified by experts during the vision scenario workshop. Trends do not necessarily form a cohesive, single targeted trend for the future. Rather, the trends point in different directions for healthcare systems and healthcare needs.

One trend has to do with financial issues related to healthcare, e.g. the cost of drugs, cost effectiveness of care, and availability of resources.

Another trend places the patient in focus and takes social factors into account, e.g. lifestyle, in order to provide care that fits the patient. Care is therefore more decentralised and integrated, and educating the patient about his or her condition is considered a vital part of care.

A third trend points towards more monitoring of people with chronic illnesses. There is a focus on co-morbidities and how to effectively manage these through closed-loop management of chronically ill patients.

The fourth has to do with drugs and legal issues. Drug tracing is an important measure to prevent counterfeit drugs from entering the market. Also the effectiveness of drugs, liability and trust are widely debated issues which influence how priorities are defined within healthcare delivery.

9.7.3   Defining the Script

In the final step, the four scenarios come to life as imaginative plays defined by scripts. In writing the scripts, it is useful to let the environmental factors enter according to a simple grouping: What is happening, how is it happening and why is it happening?

What is happening?

The scene shows a typical picture of healthcare provision and healthcare needs around 2020. Wellness has come into focus as the number of people with lifestyle chronic diseases, such as diabetes, has increased dramatically and fast. Patients have clear expectations and demands of the care they receive. Financial pressures are ever-present, and moving care delivery from the expensive secondary sector (hospitals) is prioritised, for example telemedicine is widely used to provide care at home.

How is it happening?

Most of this element is determined in the script, but a few elements enter the scene also. The use of healthcare ICT, patients' expectations and needs, and healthcare delivery models/procedures all affect how chronic disease management and therapy are performed.

<u>Why is it happening?</u>

The potentials of healthcare ICT, the nature of the patient's engagement, and the employment of self-management and monitoring schemes affect why things are happening. The outcomes will differ, however, depending on the other environmental factors that are used to define the final scenario.

<u>Writing the scenarios</u>

The final scenarios have been written on the basis of the scenario thinking process carried out this way. They have been illustrated with pictures and drawings to stimulate the reader's imagination.

9.7.4   Writing up the Scenarios

Four scenario structures can now be defined by looking at the two clusters **Care Spaces** and **Driving Forces** which each has two subplots caused by the flip and flopping of the uncertainties. The possible combinations are:

1.   Proactive Healthcare + Cost-focused

2.   Proactive Healthcare + Patient-centric

3.   Conservative Healthcare + Cost-focused

4.   Conservative Healthcare + Patient-centric

Four titles for the scenarios have been selected. The titles reflect the underlying scenario structure in the following way.

<u>1. Getting by!</u>

Though healthcare models have been changed to focus on proactive and personalised care, the healthcare budgets are under aggressive pressure from the increasing number of patients with long term conditions and the ever increasing cost of drugs. Healthcare professionals work across professional barriers in multi-disciplinary agile teams, but always under strict cost control.

Although personalised healthcare has high priority and patients are positive about healthcare ICT and feel that they can help them lead normal active lives with their condition, successful implementation has been limited and patients are not engaged in defining their own care. There is a lack of patient-to-patient communities where patients can exchange information about their diseases and thus little social pressure to change lifestyle.

ICT also facilitates - and thus has the potential to improve - communication between healthcare professionals and patients, as well as between different groups of healthcare professionals with the aim of lowering overall healthcare costs.

Due to the cost focus, neither public healthcare nor insurance companies supports programmes for healthy lifestyle initiatives, which are left to the individual. Since healthcare professionals get paid independently of the results of the care they provide, there is little incentive to do extra to change the patient's lifestyle.

2. Health Odyssey

Proactive and predictive healthcare has been instrumental in reducing the total cost of healthcare, and politicians have realised the necessity of making long-term investment in ICT infrastructure to this end. Adaptable ICT solutions that monitor vital parameters defining the overall state of patients with chronic diseases are actively deployed to support the personalised care model. The ICT solutions also support patients in managing their disease more effectively with virtual visits and televisits.

There is focus on providing proactive care with the particular aim of preventing chronic diseases and their associated long-term complications. Risk assessment is an integral part of chronic disease management and therapy and the expected yield of new medical procedures and therapies often override concerns about costs.

New care models for managing chronic illnesses are in use which seamlessly interrelate the information and the activity spheres.

Although public healthcare systems provides healthcare as needed for all, non-hospital healthcare delivery has increased dramatically and insurance companies and healthcare authorities see clear advantages in supporting wellness and prevention initiatives. Patients are included and empowered and self-management schemes play a major role in meeting the need for a healthy society.

3. Play it safe

This scenario describes a situation where the healthcare system is conservative and is not adapting to patients' individual health needs and problems. Boundaries between different healthcare professionals prevail, which limits the use of multidisciplinary teams and the exchange of medical information about patients is not practised. Due to economic constraints, new care models have to be adapted to existing care spaces before they are deployed.

Also, patients are not involved in any decision making processes regarding their care and patients are generally rather detached and disengaged and there is little social pressure in relation to lifestyle changes.

Although ICT are available they are not used to improve communication or to support patients in self-management and compliance.

There are great concerns about rising costs of new treatments and cost is always compared to the expected yield. In order to reduce the demand for new procedures, some countries have introduced a system of healthcare funding, in which citizens are given a personal health budget for life.

4. Looking for spring

In the traditional publicly funded healthcare system, financial incentives are optimised and used to promote healthy living and to provide the most effective care to patients. Reimbursement systems are highly focused on care efficiency and the care provided often determines the rate paid to healthcare professionals. Changes to healthcare models are difficult to carry through and risk assessment only plays a minor role in relation to chronic disease management.

Patients are generally sceptical about healthcare ICT and feel that they are too intrusive and threaten to take over their lives. Introduction of innovative ICT solutions such as telemonitoring and virtual visits have created some resistance. Also healthcare professionals find ICT to be too inflexible and not adaptable to chronic disease management.

However, some lifestyle initiatives are funded. As there is great social pressure on people to adopt healthy lifestyles, insurance companies have found a new market in offering insurance to support wellness and prevention initiatives. Also, patients increasingly use patient-to-patient groups to support them in dealing with their disease in a cost effective way.

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10. Chronic Disease Management Scenarios

10.1   Getting by!

Though healthcare models have been changed to focus on proactive and personalised care, the healthcare budgets are under aggressive pressure from the increasing number of patients with long term conditions and the ever increasing cost of drugs. Healthcare professionals work across professional barriers in multi-disciplinary agile teams, but always under strict cost control.

Although personalised healthcare has high priority and patients are positive about healthcare ICT and feel that they can help them lead normal active lives with their condition, successful implementation has been limited and patients are not engaged in defining their own care. There is a lack of patient-to-patient communities where patients can exchange information about their diseases and thus little social pressure to change lifestyle.

ICT also facilitates - and thus has the potential to improve - communication between healthcare professionals and patients, as well as between different groups of healthcare professionals with the aim of lowering overall healthcare costs.

Due to the cost focus, neither public healthcare nor insurance companies supports programmes for healthy lifestyle initiatives, which are left to the individual. Since healthcare professionals get paid independently of the results of the care they provide, there is little incentive to do extra to change the patient's lifestyle.

Rugby is a great sport for 10-year-old Sam who likes to play it as often as he can with his friends.

Today is no exception. He is getting ready for a big match in the school tournament and he is very excited. Sam has had diabetes Type I since he was 7 and therefore his mother has packed a bag with a couple of juices and some food together with his insulin pen and journal that explains what to do if he should suddenly feel unwell. It is better to be on the safe side even though his ePatch continuously monitors his blood sugar, and even though his morning televisit with their GP, Dr. Graham was positive, revealing that his average blood sugar looks fine.

When Sam was diagnosed with diabetes Type I three years ago, it was a great shock to his family who did not know anything about diabetes apart from what they have read in occasional articles. Sam's family lives in the far north of Scotland where Sam's dad, Simon, works as a teacher at the local school and Sam's mother, Elizabeth, works at the local shop. Sam has two siblings, Eliot and Anna who are both older than him.

No other members of the family have diabetes and therefore it was very difficult to accept that their active and healthy boy suddenly was diagnosed with a serious disease. Since the nearest hospital is more than two hours drive away, the family was also anxious as to how they could possibly deal with a chronic disease as serious as diabetes being so far away from help.

Therefore it was a great relief when Dr. Graham offered them the possibility of self-managing Sam's disease to a great extent through information, education and online communication. Sam and his parents can log on to an intelligent patient portal where they can access Sam's electronic patient journal, communicate with doctors and other healthcare professionals involved in Sam's care and get advice on nutritional issues. Sam's personal care plan has been carefully developed on the basis of his physical activities, diet, social life and general health and it will be revised and updated continuously to fit his lifestyle. The workflow is organised so that Sam deals with the same people, who are all experts on his situation and qualified to treat him.

Dr. Graham adds that the platform will make treatment more effective and improve communication between everyone involved in Sam's disease. It will also cut costs: Instead of time consuming and costly meetings it is possible to conduct video meetings between the hospital, the family and other healthcare professionals such as Sam's dietician who lives four hours away. Similarly, quick access to Sam's data and warnings of potential complications will prevent costly hospitalisation. However, the family has to pay for the installation of software and for using the portal, which they agree to, wanting the best for their son.

Most of the time Sam does not feel ill. His electronic plaster makes it easy for him to control his diabetes, because it automatically measures his blood sugar levels and transmits information if it is time to eat or

inject more insulin. Even though Sam has to get used to the attention the plaster attracts from his friends, he is happy that he can continue the life he had and play with his friends without the abruptions that traditional measurements of his blood sugar would create.

Sam has not had any serious incidents with hypoglycaemia since he started wearing his ePatch. The GCM -sensor in Sam's plaster sends data to his electronic journal which is accessible to his GP and the hospital. At one time the data showed inconsistencies in the blood glucose level and the doctor immediately contacted the family. The reason was a faulty battery which the family had to replace themselves. This is frustrating for the family since they have to change the batteries quite regularly and they cost a fortune. The consequence is that Sam sometimes does not wear the plaster.

In fact the family feels disillusioned at times; they try to involve themselves in Sam's disease but sometimes the obstacles seem too large to overcome. The initial intentions of self-management and effective communication are drowning in cost control and lack of support. Due to restricted resources the monthly televisits have been reduced to once every six months, often with a nurse and not Dr. Graham consulting the family. The hospital has also decided to close down the popular online patient-to-patient community for patients with diabetes which makes the family feel as if they are left to deal with the disease all by themselves.

They are also very worried about the expense they are facing. Due to the increase in diabetes 1 worldwide, the public health care support to patients with chronic diseases has been reduced by 20 %. At the same time hospitals are no longer offering free ePatches to patients or dietary advice due to the high cost. On top of this, the insurance companies are raising the premium for persons with chronic illnesses and withdrawing support programmes. Using the electronic plasters is very expensive for the family and

they may have to resort to using cheaper options which will also be more time consuming and inconvenient. Fortunately, the family is covered by a private health care scheme through Elizabeth's employer which absorbs some of the cost, but she is extremely worried that the family cannot pay for the best treatment for their son if the expenses grow further. She dreads to think how this instability will affect her son in the long run, knowing only too well the long-term complications of diabetes.

Meanwhile Sam is ready for his rugby match. He ties his shoelaces, grabs the rugby ball and smiles at his mum and dad before running out on the field, ready to give it everything he has got.

10.2 Health Odyssey

Proactive and predictive healthcare has been instrumental in reducing the total cost of healthcare, and politicians have realised the necessity of making long-term investment in ICT infrastructure to this end. Adaptable ICT solutions that monitor vital parameters defining the overall state of patients with chronic diseases are actively deployed to support the personalised care model. The ICT solutions also support patients in managing their disease more effectively with virtual visits and televisits.

There is focus on providing proactive care with the particular aim of preventing chronic diseases and their associated long-term complications. Risk assessment is an integral part of chronic disease management and therapy and the expected yield of new medical procedures and therapies often override concerns about costs.

New care models for managing chronic illnesses are in use which seamlessly interrelate the information and the activity spheres. Although public healthcare systems provides healthcare as needed for all, non-hospital healthcare delivery has increased dramatically and insurance companies and healthcare authorities see clear advantages in supporting wellness and prevention initiatives. Patients are included and empowered and self-management schemes play a major role in meeting the need for a healthy society.

Because it is Wednesday morning Bernhard Grossmann receives two messages on his smart device, one reminding him to change his body sensor and one inviting him to step onto the electronic scale.

He does both, but after weighing himself he is slightly annoyed: He knows he went a bit overboard last weekend when he had a night out with the lads, and it shows. When prompted, he decides to allow his latest weight reading to be entered into his EPR anyway (and therefore also be accessible by his GP); the slight increase is not enough to set off alerts, and he feels that it will inspire him to go to the gym after work to burn some calories.

Bernhard is 32 years old, lives in Heidelberg with his wife Angela and their two young children and works for a building society with offices in Mannheim. He commutes by car once or twice a week; the rest of the time he works from home or calls on customers. Bernhard likes his job, though its rather sedentary character is not the best for him.

Bernhard has been overweight since his early teens, and he was diagnosed with hypertension during his regular check-up two years ago. This made him decide to visit his family GP Dr. Kronk who examined him and set up a number of tests. When all the results were in Dr. Kronk invited Bernhard and Angela to televisit his office to discuss the findings and together decide on a course of action.

In addition to hypertension the results showed elevated blood cholesterol and blood glucose at the high end of the normal range. Bernhard was at risk for developing heart disease and diabetes Type II.

Because Bernhard's blood pressure is not dangerously elevated, rather than immediately prescribing medication Dr. Kronk suggests a combination of monitoring and lifestyle change. This regimen, if adhered to, will have the added benefit of over time reducing the premium of the private health insurance that the Grossmann family has acquired in addition to public healthcare, all the while making sure that any signs of Bernhard's condition deteriorating are picked up right away. Dr. Kronk stresses the importance of getting more exercise, of eating healthier and Angela's role in this as the primary cook in the family. With Angela's support Bernhard agrees to this plan; he does not feel ill, and he prefers not to take medication if it can be avoided – this makes him feel more normal. Another series of tests is lined up for three months further on.

Now, two years down the road, Bernhard still gets the occasional urge to pig out on pizza, chips and other unhealthy food, but he is in much better shape as a result of his community sponsored membership at the local gym. His BMI is down from 30 to 27 and still decreasing, thanks mainly to his loving wife's ministrations in the kitchen. And even better, his cholesterol and blood glucose are down and his blood pressure is in control. He was taken off ACE inhibitors 6 months ago after having taken this medication for some time, because monitoring showed that his blood pressure initially did not respond to his new healthier lifestyle quickly enough to be considered safe. While he was on medication Bernhard had

configured his monitoring system to alert him if he forgot to take his daily tablet. But at this point he is again un-medicated and well on his way to achieve his goal: restored health and body weight commensurate with his height.

Bernhard's body sensor monitors blood pressure and blood sugar, and wearing it has become second nature to him. It does not interfere at all with his daily activities, in fact he sometimes totally forgets that he is wearing it and therefore appreciates the weekly reminder to replace it. He is excited about the next generation of body sensors, which will also monitor blood cholesterol, thus making his 3-monthly visits to his GP unnecessary. To further support and encourage him Bernhard has been offered the opportunity to be among the first to test the new sensor in Germany. This also means the inclusion of cholesterol numbers in his personalised care plan, at least while the test is running. He hopes the results are so promising that this change becomes permanent. Though he likes Dr. Kronk he prefers to see him as little as possible, because this means that all measurements of his vitals are in the normal range.

Before logging on to the company network Bernhard sends a message to his gym group that the Grossmann family will be there tonight around 6:30. The gym group began as a virtual group of overweight people at risk for long term complications, which motivated the formation of a local real-life group whose members are helping each other, inspiring each other and competing with each other to get slimmer and healthier. Bernhard enjoys the good-natured bantering in the group and Angela in addition to the exercise also exchanges recipes and gets ideas for new healthy, tasty dishes. Some group members have become actual friends of the family.

Bernhard works on his computer all morning; he is regularly reminded to get up and stretch or change the height of his desk to avoid stressing the same parts of his anatomy all the time.

At lunchtime he prepares a light meal from the stock of food items in the refrigerator. Each container and package flash the approximate calorie count and energy distribution on his smart device to help him make the right - or at least informed - choices. On the days when he works out of the office he very often brings his own lunch, rather than going out and subjecting himself to temptation.

After lunch he gets in his car to call on a potential customer in Ludwigshafen. Paying for petrol on the way his smart device again flashes dietary information about the appealing goodies on display near the register. But he holds his sweet tooth in check, because he really does not like to see those high calorie counts. And one visit to the gym can only counteract so many excess calories. Instead he buys an apple and feels very good about himself.

Before driving on he checks his smart device, and as expected he has received several messages from gym group members who also plan to work out tonight. They each set a target for the level of workout they want to achieve when they meet.

After the meeting with his customer Bernhard messages Angela that he is on his way home. Back at the house he parks his car and enters the house. Angela is already there, and she and the kids are ready.
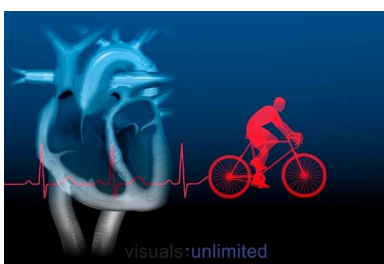
They all get on their bicycles to ride to the nearby gym, even little Rolf who is five.

When they arrive at the gym Bernhard's smart device registers the energy utilised during his bike ride. Angela and the children frequently accompany Bernhard to the gym; they have a family membership. The gym has a pool and all kinds of equipment suitable for both adults and children. It is important to Bernhard and Angela that their children get into the habit of exercising regularly from an early age. They want to be good examples and to make sure that the next generation of Grossmanns will not have to deal with Bernhard's problems. Neither Angela nor the children are being monitored; they are not considered at risk. But seven year old Stefan is very interested in all the new technology, and he follows his dad's progress closely. He would very much like it if his own bike registered his efforts.

The exercise equipment at the gym can also communicate via the intelligent network, and Bernhard's hard work will be monitored and recorded. He gets on the treadmill and keeps going until he works up a healthy sweat and gets his heart pumping. At decreased intensity he keeps going until he has reached the goal he set himself earlier in the day.

10.3   Play it Safe

This scenario describes a situation where the healthcare system is conservative and is not adapting to patients' individual health needs and problems. Boundaries between different healthcare professionals prevail, which limits the use of multidisciplinary teams and the exchange of medical information about patients is not practised. Due to economic constraints, new care models have to be adapted to existing care spaces before they are deployed.

Also, patients are not involved in any decision making processes regarding their care and patients are generally rather detached and disengaged and there is little social pressure in relation to lifestyle changes.

Although ICT are available they are not used to improve communication or to support patients in self-management and compliance.

There are great concerns about rising costs of new treatments and cost is always compared to the expected yield. In order to reduce the demand for new procedures, some countries have introduced a system of healthcare funding, in which citizens are given a personal health budget for life.

The year 2020 started off with a medical scandal in Sweden regarding a young diabetes Type I patient who had died as a result of counterfeit insulin he had bought on the Internet. The case opened up a can of worms. Before long newspapers were bringing reports on the huge "black" Internet drug market in Sweden. The case immediately became a hot political topic but no one had foreseen what was about to happen: by the end of January 2020, 53 people – all diabetics - from different EU countries had died from counterfeit insulin and many more had suffered serious complications. EU legal action was put into motion.

In the months that followed, it transpired that the people who had died had bought insulin via the same Internet site. The insulin was not only counterfeit; the concentration was nearly twice as high as was declared on the label and in the enclosed leaflet. As the investigation progressed more and more counterfeit drugs sold via the Internet were discovered. Some of the biggest European pharmaceutical companies joined forces and proposed that an intricate drug tracing system had to be put in place. The technology to do so already existed but so far the various European governments had all been very reluctant to endorse the system because it was very expensive.

In essence the system would be able to read and analyse all prescribed drugs. When the pharmacy receives an electronic prescription for a patient, the information would also be transmitted to a small device, similar to a very small kitchen scale. Once the prescription had been filled, the pharmacist would then need to place the medicine bottle on the device and instantly get a reading of the content. The data would automatically be compared to the original electronic prescription and the device would turn either green or red. In case of green, the label with the right instructions would be printed out automatically. In case of a red light, something was obviously wrong. This could be either the medication itself, its strength, quantity etc. and it would be impossible to print the label until the mistake was corrected.

As an additional security measure, small sensors in the labels and the bottle would compare data to ensure that the right label was placed on the right bottle. If a wrong label was placed on the bottle, the label would turn red and be impossible to read. This should prevent the bottle to ever enter the patient's hands. Pharmacists, healthcare professionals and politicians all over Europe are enthusiastic about the system but no one is ready to implement it just yet because it is too expensive.

Bo and Ingeborg Nilsson have followed the medicinal scandal with great interest. They are both in their early seventies, retired and live in suburban Stockholm. They have both suffered from diabetes Type II and hypertension for several years. They have been hospitalised numerous times with complications. Despite this, they actually know very little about their disease and they do practically nothing to try to manage it. Their lifestyles haven't changed since they were diagnosed. They are both overweight, smoke, drink heavily and never exercise. Bo has been injecting insulin for a year now and Ingeborg will most likely have to start soon too.

For years before they were actually diagnosed with diabetes Type II, their health was poor. Their GP had told them several times that they were at risk for developing diabetes 2. Had they received the proper information, predictive care and especially

support in changing their unhealthy lifestyle, it is very possible that their diabetes could have been prevented. Unfortunately, as patients the Nilssons required, and require, much more support, involvement and education than the average patient and a lot more than is provided by the healthcare system. They were only ever given some leaflets with the most basic information about diabetes.

The Nilssons get their glucose level checked every three months by their GP. Each time one of them has been hospitalised, they have been seen by different doctors and nurses and each time they have had to relay their entire medical history. The Nilssons don't understand why their GP and the hospital staff don't have some kind of common system allowing them to share information. Apparently, the electronic patient record (EPR) system isn't very efficient; it seems that each doctor simply just records his assessment in the EPR without consulting or taking into account what other doctors have entered on earlier occasions.

They have recently been informed that the treatment for certain diabetes related complications is too expensive compared to the expected yield. The public healthcare system will therefore not offer this treatment, especially now that they've reached the limit of their personal health budget. They would have to go to a private hospital which they cannot afford.

In addition to deteriorating health, the Nilssons are also beginning to suffer economically. Their personal health budget has reached its limit which means that they are no longer completely covered by public healthcare. The cost of their medication is extremely high and on top of that they now also have to contribute out-of-pocket for healthcare. The Nilssons are worried. The past couple of years they have bought nearly all their medication on the Internet which has saved them a lot of money. But now with all the media and political focus on drugs sold via the Internet, they worry that they will not be able to continue buying their drugs this way. They worry less about the danger involved. Bo thinks it's all just a scam because the pharmaceutical companies are losing money.

In effect, their faith in the doctors and the entire healthcare system has diminished over the years. Each time the doctors or nurses tell them that they must take their diabetes seriously and manage it better, the Nilssons feel like small children being told off. They feel as if they are being criticised for no good reason because how are they supposed to just up and change their lives completely without any guidance and advice on how to do so. If only some kind of intelligent device or system was available which could manage their diabetes for them.

10.4   Looking for Spring

In the traditional publicly funded healthcare system, financial incentives are optimised and used to promote healthy living and to provide the most effective care to patients. Reimbursement systems are highly focused on care efficiency and the care provided often determines the rate paid to healthcare professionals. Changes to healthcare models are difficult to carry through and risk assessment only plays a minor role in relation to chronic disease management.

Patients are generally sceptical about healthcare ICT and feel that they are too intrusive and threaten to take over their lives. Introduction of innovative ICT solutions such as telemonitoring and virtual visits have created some resistance. Also healthcare professionals find ICT to be too inflexible and not adaptable to chronic disease management.

However, some lifestyle initiatives are funded. As there is great social pressure on people to adopt healthy lifestyles, insurance companies have found a new market in offering insurance to support wellness and prevention initiatives. Also, patients increasingly use patient-to-patient groups to support them in dealing with their disease in a cost effective way.

It is Friday morning and doctor Whiteley has a busy day ahead of her. She is a General Practitioner (GP) and has her own small practice in a village in North Wales. Besides herself a nurse, Mrs. Cole, and a receptionist, Miss Dean, work at the practice. When doctor Whiteley arrives at 7:45 am, Miss Dean is already there checking the online diary. A simple click on "get EPRs" (Electronic Patient Record) instantly pulls out the appointed patients' EPR from the central National Health system. As soon as doctor Whiteley turns on her computer, it will synchronise with the reception computer, thus presenting her instantly with the list of patients for the day plus their EPRs.

Friday is dedicated to her diabetic patients and the practice is therefore closed for any emergency appointments. This is a relatively new measure, instigated because the number of chronically ill patients, mainly diabetics, has increased dramatically in the last few years. Not only that, a large majority of her diabetic patients have suffered complications due to poor management of their condition. This has affected her practice's finances as the GP reimbursement system is based on care efficiency and the care provided; each time a diabetic patient develops complications the care she as the GP provides is found lacking and thus "punished" economically. In addition, her professional reputation and pride has suffered too.

Doctor Whiteley therefore found it was necessary to have a full day devoted to this group of patients in an attempt to provide more efficient and better care. By doing so she has to some extent managed to turn the situation around but there is still a long way to go. Doctor Whiteley has several ideas for more innovative ICTs, which could help improve diabetes monitoring and self-management, but the technology is still too simple and only offers monitoring of glucose level. Nevertheless, this could benefit a lot of her patients, but most of them look at her in horror when she discusses the idea with them. Most patients are sceptical about the effectiveness or simply reject the idea of being monitored by ICTs, fearing a loss of privacy and autonomy. They prefer coming in to get her to measure their blood glucose level and, as they rightly point out, this way they also get other vital parameters checked at the same time.

Doctor Whiteley and Nurse Cole work side by side weighing patients and measuring blood pressure, glucose level and cholesterol. All the devices used to make these measurements are online and connected to the REACTION platform. This saves time because the data is automatically and instantly uploaded to the patient's EPR instead of having to be entered manually. Doctor Whiteley hopes that one day a special diabetes ICT monitoring system will be available, which can measure, analyse and evaluate vital diabetes related parameters and data providing a quick and easy risk assessment. For now, limited resources prevent her from carrying out a proper risk assessment and analysis of medical data in order to create a detailed and personalised care plan for each patient. All she can do at the moment is record the data, inform and advise her patients and hope this will encourage them to manage their condition better.

The first patient this morning is Mrs Martins. She is 69 years old and was diagnosed with diabetes Type II three years ago. When Mrs Martins was first diagnosed with diabetes she became very depressed; it seemed like another blow just as she felt that she was beginning to live again after having lost James, her

husband of 42 years. Mrs Martins' husband died five years ago from a sudden heart attack while recovering in hospital after having his appendix removed. On top of that, she feels that her family and peers are blaming her and thinking she deserved it because of her obviously unhealthy lifestyle. She's also certain that they think that her cooking was essentially what killed James. Spurred by guilt and social and peer pressure, she has changed her cooking and eating habits. Light and fat-free products, less red meat and more greens, and oven-baking or steaming instead of frying are now part of her habits but she's definitely not happy about it. She feels deprived

She is terrified of developing complications that would require hospitalisation because in her mind

"hospitalisation kills you!" She is therefore trying the best she can to manage her diabetes by eating healthier food and exercising, but it's not easy, in fact she's torn between not wanting to deny herself any of life's pleasures (especially good food and wine) because she knows that life can be cut short very suddenly and between wanting to be as healthy as possible so as not to cut life short. Indeed a very complex frame of mind! She's very frustrated that her GP can't understand this and prescribe a way of life that allows her to eat her cake and have it, too.

When her daughter-in-law found out that a county-based diabetic patient group existed, Mrs Martins was at first reluctant. She didn't want to listen to sick people complain about their disease plus it was a long drive to the community centre where the weekly meetings are held. But feeling that her GP was simply informing her of her condition's progress rather than giving her the necessary support to manage it, she decided to give the patient group a chance. She was pleasantly surprised; it wasn't a case of sick people complaining at all but people like herself who needed support from people in a similar situation to their own. She finally found other people who could understand her frustration of wanting to be healthy while refusing to give up on enjoying good food and wine. The weekly meetings have helped her to deal with her condition, not least by accepting some of the lifestyle changes she has had to make because she knows she's not alone.

Today she's seeing her GP for her usual tests which are done every three months. This morning her glucose level and blood pressure are slightly elevated, but she has lost 4 pounds. Doctor Whiteley tells her that she really should reconsider investing in ICT enabled glucose monitoring system because it would probably help her resist eating certain foods if she was able to see instantly how it affects her blood sugar. And, her GP adds, she's pretty sure the costs are covered by her private health insurance.

This much is true because Mrs Martins has a private wellness and health insurance, which is covering most of the cost of the local "Diabetes Gym" she has joined as well as the cost of the consults with her dietician. The costs are not really the problem as much as her general distrust, and lack of skills, in these modern computer technologies. To her mind computers have already taken over too much in our lives and she is not about to subject herself to monitoring by yet another ICT system or device. She prefers her patient-to-patient group; she feels that she gets the right amount of support and peer pressure from the group to help her live healthier, and this is plenty monitoring for her. Yes, she could do better but she wants to do so without giving up her privacy and autonomy to some ICT monitoring system.

11. Table of figures and tables

Figures

Tables

12. References

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